HIT Policy Committee
Final Transcript
September 14, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everyone. Welcome to the 16th meeting of the HIT Policy Committee. Again, this is a federal advisory committee, which means it's being conducted in public, and there will be a transcript of the meeting on the ONC Web site. Just a reminder for workgroup members to please identify yourselves when speaking for attribution's sake, and let's do a quick introduction around the table beginning on my right with Commander Weiner.

Michael Weiner – Defense Health Information Management System – CMO
Michael Weiner, Military Health.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Scott White, 1199 SEIU.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health, Denver Health.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women and Families.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst, Intermountain Healthcare.

Paul Egerman – Software Entrepreneur
Paul Egerman, software entrepreneur.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, ONC.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP
Rick Chapman, Kindred Healthcare.

Deven McGraw – Center for Democracy & Technology – Director
Deven McCraw, Center for Democracy and Technology.

Neil Calman – Institute for Family Health – President & Cofounder
Neil Calman, Institute for Family Health.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Charles Kennedy – WellPoint – VP for Health IT
Charles Kennedy, WellPoint.

Gayle Harrell – Florida – Former State Legislator
Gayle Harrell, former state representative, Florida.

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
Mike Klag, Johns Hopkins.

Judy Sparrow – Office of the National Coordinator – Executive Director
I believe we have a number of members on the telephone. Is anyone on yet?

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Adam Clark, FasterCures.

Judy Sparrow – Office of the National Coordinator – Executive Director
Adam Clark. Thank you. Anyone else? All right. With that, I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Good morning. I appreciate all of you who were able to find this meeting room today. I understand that several trails of breadcrumbs were laid out, and most got consumed by hungry attendees. But nevertheless, here we are. Thank you all.

This is, as Judy said, the 16th meeting of this group, and I'd like to take a moment just to recognize Judy and her colleagues for the incredible job that she has done. When we stopped counting, which was about three or four months ago, we had had, I think, 170 or 180 meetings of the federal advisory committees and their workgroups in about a 16-month period. And we probably are over 200 by now. And that really, that number is astounding and testimony to the organizing power and capabilities of Judy and all of you who have stayed with us, and many others who are probably not listening right now who have participated and donated their time. If we've accomplished anything up to now, it's been in large measure because of that community support that we've enjoyed throughout this and the hard work of ONC's staff.

We are now firmly, as you will see today, into the next season of meaningful use. And we also are continuing to deal with not only issues that prepare for meaningful use, but the fundamental issues that are important to the long-range success of our enterprise, but does not need to be dealt with in order to get meaningful use and the regulatory and institutional framework supporting meaningful use up and running. So some of those, you will be hearing today. One issue that you'll be hearing about that we hadn't initially put on the schedule has to do with accessibility issues, which we committed to our colleagues on HHS to look at, at this coming round of meaningful use, and we'll be hearing about quality as well. The governance area is something that we are required, as you know, to deal with as a legislative matter, but also is very important to the future of our goals of interoperability.

A lot still to do. We will pretty soon be up to our ears really in thinking about the next stages o meaningful use, though we do want also to learn something from the experience of stage one of meaningful use. I can tell you that I've been traveling around the country. I've probably been in 10 or 12 states in the last couple of months. Everywhere I go, I meet with hospital executives, physicians, state and health plan representatives, and there's a lot of work being done, a lot of questions being asked. I still think our success in attaining meaningful use is still going to require a lot of work. But we have a network of regional extension centers. They do exist. I meet with them almost everywhere I go.

We have a group of engaged state grantees who are thinking hard about interoperability. We have community colleges enrolling members in a first class of health IT personnel for training. And we have a consumer community that's actively watching and participating in the discussion about consumer protection and security of electronic health records. So there's a lot bubbling out there beyond the beltway, and a lot to learn, a lot to see. Anyway, welcome again, and I'm going to let Paul now go through the agenda in more detail. I guess, also, we need to look at the minutes from the last meeting.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I also want to join him in thanking the ONC staff, Judy in particular. With that many meetings and the lead ONC staff people and all the workgroups, it can't possibly be done without an excellent staff, and so congratulations. Thanks to the staff members, and congratulations on getting such a great staff in the office.

First, I want to go over approving the minutes. If there's anyone who would like to move that, we approve the minutes.

M
I move.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And second?

M
Second.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay. And any further discussion, corrections, edits? Okay. All in favor?

M
Aye.

M
Aye.

M
Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any opposed? And abstained? Great. Thank you. So we're going to have a number of updates from important workgroups today beginning, as David mentioned, the season of the stage two and three meaningful use objectives and measures. So we'll talk to you about the process we have for doing that. Then we're going to introduce the quality measures workgroup, which is looking at quality as really the persistent value of this whole meaningful use incentive program whereby we can both measure and continuously improve the work that we do to improve the outcomes for patients and the population. Then talk about the governance workgroup, which is looking at governance for NHIN, one of the statutory requirements of this group.

After lunch, we'll come back and talk about the new work of the information exchange workgroup in both the provider directory taskforce and the public health taskforce, and then get some advice on the accessibility issues, as David mentioned, as input to the meaningful use discussion. And conclude, as usual, with the public comments. Any other changes to the agenda? If not, then I'd invite George to come up and talk to us about the plans for the meaningful use workgroup in stage two/three.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Acknowledge and thank my workgroup members, and here's my slide. Here's our process for developing the meaningful use measures for stage two. First, well, let me go through, and then I'll describe quality measures in a second. On September 22nd is going to be our big, in person meeting, all day meeting where the workgroup comes together to develop draft recommendations for stage two. We're using as our input is the CMS final rule, of course, which includes stage one and couple of stage two measures. Our public hearings that we've held over the last year, which include some specific recommendations about meaningful use, which we've now summarized, and we'll produce a public document for that. And just in general, the advice, high-level advice that we got at those public hearings.

The Gretzky Group Report by NQF is suggesting how to approach is working on the quality measures. I'm going to come back to that in a split second. And, of course, public input, which so far is mainly through our public hearings and through our blog, but there'll be further public input in the process.

You'll be hearing from the next workgroup, the quality measures workgroup, and so we are, I would say, somewhere between deferring and collaborating on the quality measures for stage two, so perhaps David Lansky will elucidate that further, but basically the idea is this workgroup is very focused on developing these quality measures for stage two, and so we'll work. I mean, it has to fit together with the structural measures and the goal of the thing has to be one piece, and so we're basically still working at exactly what it looks like for the two groups. But we have the right team in the quality measures workgroup.

Then on October 20th is our next policy committee meeting, so we'll be presenting the results of the September 22nd meeting to you. Then in November and December is the opportunity for public input and RFI. Then for the next two quarters, this next half year, we'll be monitoring stage one submissions, so it's still a little bit early, but we hope to see activity then and see how it's going and, for example, there are menu options, which ones are chosen and so forth and just the general volume of submissions for stage one. In the second quarter, we'll be then submitting. We'll be finalizing our draft recommendations to the policy committee, and then hope to submit final recommendations, that you will be submitting final recommendations to ONC at the end of the second quarter. Other things you'd like to explain, Paul? Questions?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Maybe to both David and to George, is there any way of quantifying or estimating the stage one adoption rate and selection of measures, as you just suggested, George, through a pre-survey, an intentional assessment? I know we all have our kind of qualitative experience of traveling around. But any way short of waiting until next spring to get some preliminary data or predictive data on what's going to happen?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
The adoption workgroup would probably be the best to answer. David, do you …?

David Blumenthal – Department of HHS – National Coordinator for Health IT
There are fairly frequent non-scientific samples of the various communities, so there was a survey of the CIOs that are members of CHIME, the College of Health Information Management Executives, yes, that one. And … I saw yesterday, and that it's interesting, but not, I think, nothing you sort of hang your hat on. It had like a 12% response rate or a 14% response rate, not very useful. And there have been a number of those over time, so I think we could probably learn more, but I really don't know that we would want to make a policy based on intentional data. I think we're likely to learn more about the difference between expressed intent and behavior than we are about what actually happens.

There's a lot of communication with the public and with providers that is going to be going on over the next six months. The Center for Medicare and Medicaid services is going to be intensively educating providers about the meaningful use incentives. The Office of the National Coordinator is going to be doing the same with consumers and with some providers. So I think that there still is a lot of lack of information among large segments of the community, and this is still early in terms of the socialization of this set of content.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Christine?

Christine Bechtel – National Partnership for Women & Families – VP
I just wanted to follow up on David's comment, David Lansky's comment, and I understand, Dr. Blumenthal, the hesitation I think we all share around intentional data. What I am wondering about though is I think there are two communities of folks who are uniquely positioned to give us a better sense of what's happening in the environment, and it might be a good idea to set up some ongoing conversations starting with the September 22nd workgroup meeting. And that, I think, is the RECs and the

vendors. I think I'm particularly interested in what they're seeing now in terms of even an initial reaction to which menu set options folks are selecting and why, and what they're not selecting and why. And then being able to sort of have that same conversation over time, I think, would be very helpful, as we move into the spring as well.

Paul Egerman – Software Entrepreneur
First, I just want to say I really like the slide. But I do have a question or concern about the schedule, which is, how are we going to coordinate meaningful use stage two according to this schedule with the entire certification process because we already made a recommendation? The certification workgroup made a recommendation that this policy committee accepted that the certification criteria for stage two had to be completed or well known by April 1, 2011.

The reason for that is you go through the entire sequence of events that are needed to develop software and to certify and distribute. There's not enough time. I mean, even April 1st only gives you 18 months until the beginning of the stage-two eligibility period, October 1, 2012. It seems to me that this schedule, we need to either accelerate the schedule, or you need to understand with the schedule, all you're going to be doing is either raising or lowering the bar. That this is not a schedule that provides for additional functionality in these systems beyond what's already been certified.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul, do you feel that the November/December timeline is too late, or just that the way we've written down quarter one, quarter two is the problem?

Paul Egerman – Software Entrepreneur
It's the quarter one, quarter two process. I mean, if what you're telling me is if by November/December, it was fairly well know what was going to be included, then maybe I misunderstood it. I thought you were just requesting information in November or December.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
We'll have to process the public input. I mean, so the other force is seeing what happens in stage one, and so that's our tradeoff. So we need to make a process that works, working with certification on the one hand. On the other hand, we want to have as much time to look at actual use of stage one as possible. I think that we're somewhat flexible on that. I think the November/December RFI, we have to plan right now when that's happening, and that's why I was mainly making sure that that's early enough for you guys. As long as that's early enough, then I don't know, Paul. Do you want to comment?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. Actually, if you recall our discussion our discussion at this table about the April kind of timeframe, and we chose carefully the word —available" versus, I think, committed or approved, and that was to say there needed to be some way of getting the thoughts out there, and so that we've put into place this RFI process to at least get that, and by April, we should have some digestion of the public input to the initial draft recommendations. The reason for Q1 and 2, April is the earliest that actually people can apply for it and May is the first day can get payment. So it wouldn't be until then when it would be reasonable for us to even react to the market in terms of what they've submitted further for the first available time. That's how it's been driven. Yet, we try to make as much out there and feedback incorporated by April, and that's sort of the best we could do.

Paul Egerman – Software Entrepreneur
I'm not sure I'm hearing something a little bit different because if I heard George right, what I first though he was saying is November/December, we'd have a pretty good idea. If we had a pretty good idea of the functionality….

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
…process the information.

Paul Egerman – Software Entrepreneur

Pardon me?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair We'd then have to process the information. I was asking if the RFI had to be earlier than November/December to meet your timeline, and I don't think we can do it much earlier than November/December anyway, but how long would it take us to process the input? It's not a long period of time. The problem is seeing what happened with stage one of this thing that's really pushing us more than this other part. So I think we'll have the public input in time. We just won't have stage one in time.

Deven McGraw – Center for Democracy & Technology – Director
I think what we really need to get out by April ideally is anything that's going to require additional functionality in an EHR, right? I mean, if I'm understanding the reason for making sure that we get something, some signal to the market is if we're going to require the EHRs to be compatible in other ways or to adopt additional functionality, we need to know what's new that's going to be on the table. To me, assessing what happens in Q1 is all about sort of what of the functionalities that are already in the EHRs are people adopting, and do we need to stress more of them in stage two because they didn't get adopted in stage one, but maybe that doesn't change what the EHR vendors need to do because we're not throwing anything new at them.

Paul Egerman – Software Entrepreneur
Certainly, as I say, if you change what I call raising or lowering the bar, that's not a problem. If you were going to say we want greater compliance or something that was previously optional is now mandatory or vice versa, that's not a problem. It's if you say, well, now we want to add radiology to the mix. Well, if you did say radiology, that's not enough. What's really needed by April 1st is pretty much like what you would have at least in the first draft of an interim final rule. You'd say this is what we're looking for. This is the detail for this functionality. Then I think the vendors would have a chance to get it all done.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think some of the …. Sorry.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
Well, perhaps Paul wants to answer that question. I don't want to change the train of thoughts because my question goes to a different issue. I don't want to step on this topic before we get into another one. Go ahead, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think part of what we'd be looking for, let's take two extremes. Nobody is applying in the first year because they're so busy trying to get to the things, and their tools in place, and the use in place in order to quality. That would be a signal that, gosh, I don't know whether we'd want to be adding that much more. Let's take the opposite. We're getting a really healthy response.

Then we had certain placeholders in stage two, as an example, and they did represent some new functionality. You might want to, you would calibrate the pace with which we've pursued the new functionality based on response, I think, to some extent, to the existing stage one criteria. Does that make sense? That's how it could change what new functionality you might add and how aggressive you'd be with moving along towards 2015.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
It sounds like the risk is more that we'll take things off based on response rather than add new things we hadn't thought of before, which is still an issue for you because that would mean that we've taken off a criterion that you put in certification criteria for that maybe would have been unnecessary. But either you see stage one before you announce the certification criteria, or you don't see stage one before you do.

Paul Egerman – Software Entrepreneur
To me, it's not a problem if there's too much certification criteria. I'm not worried about that. I would actually err on the side of that because if you don't include something in stage two, there's probably a good probability that you could do it in stage three. So I would just say that if part of your schedule is that at the end of December you could give some strong signal as to whether or not you think there's additional functionality, and perhaps even get people started on whatever process NIST and everybody else needs to do to start drafting the criteria for it. That would be very helpful, even if it causes people to overreach. At least they'll know what it is they're supposed to be doing.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
Thank you. To change the subject slightly away from that, well, before I go into my new topic, let me go first to what you all were talking about when you're talking about the certification criteria. The vision had been at stage two, we're moving up requirements on interoperability. That would certainly affect the certification criteria. Do you have any idea of, because, of course, we want to have that exchange of data become really the core element in stage two? Are you looking for additional functionality from the vendors to be able to meet that? There's so much dealing with the privacy and security elements that have to be addressed. The HIEs have to be out there, so are we going to continue to push for that interoperability in stage two?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair Interoperability is definitely on the table for stage two, but I think, at this point, if I say anything without reviewing all the other workgroups, I don't want to. Paul, do you have a better answer than that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
No. I think even the signals in the final rule said that interoperability is going to be a big focus of the effort in stage two, so I think that's a pretty strong signal, and that's another example where feedback from stage one will be very important because it's not always the sourced end. It's really can, let's say, public health agencies all receive this or what can ….

Gayle Harrell – Florida – Former State Legislator
On my second question dealing again with specialties, certainly in stage one, we did not truly address the needs of specialists. To make this a national program where everyone has a comprehensive EHR, you need to bring those specialists in. Are you envisioning perhaps more in the way of public hearing, reaching out again to those specialty societies? Are you going to get input from them into what will assist them to qualify for meaningful use?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
I can give an initial answer. I think that the specialties, the structural measures largely cross the specialties. The quality measures are the ones where the differences are most pronounced, and that's exactly what the quality measures workgroup is going to be working on. David will probably be covering that in the next section. David Lansky will be covering that in the next section. I think that's, among the structural measures, I have to look again, but that's not where most of the problem was.

Paul Egerman – Software Entrepreneur
If I could just follow up on the comment that Gayle made about interoperability, in my mind that's a major aspect of stage two certification that would be great, and it would be easy. It would be helpful to signal by December what are the aspects that will be included. In other words, what are the standards, especially since some of those standards are already defined, and that's helpful for a lot of reasons. One is you get the vendor community and everybody oriented around it. But also, we compare the interoperability functionality with other functionality. It doesn't involve necessarily changes in clinician workflow or significant changes in changing the way people enter data. So it's a good thing to be doing in stage two is to accelerate our efforts on interoperability, so I would encourage that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
This looks like a great process. The adoption and certification committee have committed to pull a group together to look at some of the adoption issues, and we really wanted to focus a lot on the smaller providers within that particular hearing, and that isn't set the date yet, but I think that will be good feedback for the process, particularly as it deals with some of the challenges that the rural or some of the smaller providers or smaller hospitals might have.

So again, I don't think, by October 20th, we'd have that information. But certainly during that RFI period, we should be able to provide some meaningful feedback into that process. And I also don't think you're going to lack for comment between October 20th and the time you finish, even though the chime or that anecdotal or scientific data won't be there, I think we're going to get a lot of information.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I'll just follow up on a couple things. One, Gayle, and the specialists, so just like interoperability is really a key for us for stage two. I think, on the specialty area, one of the placeholders we did have that wasn't in the final rule was the return, sort of the roundtrip. In other words, when you refer somebody, getting timely feedback. You can see how that cuts across all specialty areas. I'm not saying that's what would do, but it was something we had proposed in the initial, and you can see how that's of benefit and involves the specialists.

And respond to the earlier question as far as feedback from the user community, the provider user community, I would probably say that they have not really spent a whole lot of time so far getting ready. I think people have looked at some of the requirements, but have not engaged in the strategy. So it's probably, I don't even know that there's that much data today to say what are they going to be doing in the initial use, so you might be seeing that closer to the end of the year, beginning of next year, as they prepare.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Richard?

Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP
To follow on to Paul's comment, we have a classic dilemma here with timetables that we've preset and then a process that's going to require some attention. And in the adoption group, we'd talked a lot about getting feedback and barriers to adoption along a number of topics and a number of different groups, both the large and small groups, and whether it's due to implementation or other things. And I think that's going to be a constant – I think we're going to have to be prepared to not get everything turned around.

We're going to have to kind of ride our bike and fix it at the same time here, which is, we're going to get the feedback, but only so much of it will be able to be put into phase two, and some will have to be staged later even into three or whenever we get there because I think we're going to find out there could be a showstopper along the way with either implementation or the extension groups as well. So I think we just need to set our expectations that we won't get as much quality feedback on meaningful use if in fact there are other barriers to implementation that may have prevented just utilization or process metrics from being used. We made the assumption that if in fact we define these process metrics and that we'll basically define utilization that eventually if people layer on top of it, those will lead to meaningful use.

First, and in order of this, we have to make sure they're being implemented correctly. Second, that the process metrics don't tell us anything alarming as far as utilization of the functions we've already said. And then I think, third, just who is actually achieving and what percentage, and that'll tell us how fast we can go. But as we consider – I would urge us, as we consider phase two, to stay again as generic as

possible because you're going to have to implement or start the process in place before we know enough to change meaningful use too significantly. At least I throw that out there for a discussion.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Charles?

Charles Kennedy – WellPoint – VP for Health IT
In the stage one meaningful use criteria, we dropped the administrative transaction component, and I'm wondering. I don't remember the exact reference, but it'll be back. Do you see on the September 22nd meeting, us getting back into the issue of administrative transactions, and also electronic submission of quality measures? Is that going to be played out in this discussion?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Yes.

Charles Kennedy – WellPoint – VP for Health IT
Yes. Okay. Great.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair I'm going to make sure it's on our spreadsheet.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If in the second quarter the policy committee makes recommendations to ONC, ONC and CMS, notably CMS, will take those recommendations and fashion a notice of proposed rulemaking. And that notice of proposed rulemaking will then be subject to comment, and then will be redrafted into a final rule. So we're going to have some time to learn more about meaningful use stage one after April, before we finish the second iteration of meaningful use and the second iteration of the standards and implementation specifications and certification criteria.

There's a dynamic sort of sequential process that enables this group to set some directions, but us to then take advantage of experience in modifying those recommendations. I hope that that serves to some degree to do what we try to do in stage one, which is to use the policy committee's recommendations as a signaling mechanism, while as part of the procedures of the federal government, ONC and CMS have to remain silent about what it was actually doing, what they were actually doing. So I think there will be 18 months of warning. There won't be 18 months of certainty. But clearly we have to conduct ourselves in a way that uses the warning in a responsible way.

M
Just really to David and Christine's earlier questions around how we're collecting input, particularly from the regional extension centers. We've set up a process. We've got a meaningful use Vanguard cohort in our RECs, the move cohort that is where each REC is identifying sort of the leaders in its area. And we're collecting data from all of them on how they're doing in the first implementation of meaningful use, and that's kind of how we're getting a jump-start on collecting data. Obviously that is primarily from the priority primary care providers that we have identified, but some of our RECs are serving broader populations besides what they're getting from the grants as well.

Christine Bechtel – National Partnership for Women & Families – VP
…coming in and….

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair So we will begin in the fall starting to collect data. We are working. We're actually launching it later this week, and we will begin to start. We've been developing tools for how that data will be coming in, but it will give us some sense of how the different objectives are shaping up relative to each other.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Art?

Art Davidson – Public Health Informatics at Denver Public Health – Director
Yes. George, I just wanted to understand a little bit more how the numbers, the dates that are up there relate to our experience with stage one meaningful use. I think it was the middle of July of '09 when we first presented the matrix that we started with.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair It was the initial version in June, and then the final is August.

Art Davidson – Public Health Informatics at Denver Public Health – Director
August. Then the final rule came out how much after that?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair A year, more or less.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Given what I think Paul got us down this path of we need to give the vendors 18 months, and I think we back calculated that to the end of June of '11. Is that right?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
April ….

Art Davidson – Public Health Informatics at Denver Public Health – Director
But the 18 months would be?

David Blumenthal – Department of HHS – National Coordinator for Health IT
October 2012.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Are we able to telescope the timeline from when we gave our final matrix to where we will have a final rule for stage two and still accommodate what Paul has been recommending for the vendors?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Telescope which part of the timeline? Our production of our recommendation or what … after …?

Art Davidson – Public Health Informatics at Denver Public Health – Director
Well, I think, when CMS has a final rule, isn't that what we're trying to get to?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think the strategy that David Blumenthal was saying in terms of how stage one came about is sort of what we're trying to pursue, knowing that we have to fix the car as we're driving it. And I think what I heard from Paul Egerman was, and if you are a bit ahead of ourselves, that's less of a problem than if there's some new requirement that comes out. That would be a real challenge for vendors and providers. I think, if you look back at the July 2009 matrix, it was pretty darn good as far as what came out, certainly in the categories, and there are things that may be were backed off a bit in the name of flexibility. But that still was a really good signal for vendors and providers, I think.

We're hoping to achieve that same kind of balance, not wanting to get way ahead of the market, but certainly on the roadmap. So our original thought was the matrix was essentially a roadmap, and the timing may be off, and the thresholds, etc. But we're trying to stick with the roadmap philosophy to give signals to the vendors, to the provider groups, and then they can, as Paul mentioned, or I think Marc said, we'll get feedback. The combination of that, I think, will be a fairly good predictor.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. We obviously have taken very seriously CMS and ONC the advice that you all have given us, and we intend to do that in the future. We are not bound by it, and there are many moving parts in the federal

government, and we receive input from all of them. And so it's not always possible to predict with certainty what will come out the other end of this process, but we will pay close attention, and I assume that having seen the results of the last go around of meaningful use that the industry will also pay close attention to what you recommend. But presumably they will also know that the federal government isn't bound by the recommendations of the federal advisory committee, however sound persuasive and authoritative those recommendations may be.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, George. Just a word of introduction for David: I'm taking off my chair of the policy committee hat and putting on a different chair, the chair of the working group on quality. This is an extremely important group. There was a lot of very intensive work done around quality measures for stage one of meaningful use, and the NPRM actually included in excess of 90 measures for eligible providers and, I think, in excess of 40 measures for hospitals. And they included a fair number of specialty specific measures for eligible providers. We didn't get down to the level of neuro ophthalmology and oncologic dermatology, but we got to 10 or 12 of the major specialty groups.

What we found in the process of going through that was two things. First, the … quality measures were developed in a world in which electronic health records were not widely available, so they were heavily dependent on claims data and chart review. But more claims data than anything else because that's where the lamppost is, so we look under the lamppost. We weren't thinking broadly enough or carefully enough about the way we can find useful measures, more meaningful measures in an electronic health record environment, measures that are better risk adjusted, measures that are more sensitive to clinical data, measures that may be longitudinal since the electronic health record can fairly effortlessly develop serial data about a single patient, which is very hard to do in a paper world.

Judy Faulkner – Epic Systems – Founder
(Inaudible.)

David Blumenthal – Department of HHS – National Coordinator for Health IT
Pardon.

Judy Faulkner – Epic Systems – Founder
I just wouldn't say ….

David Blumenthal – Department of HHS – National Coordinator for Health IT
Theoretically effortlessly, that's right. Judy, we are so respectful of your talents that we just assume it's effortless.

Judy Faulkner – Epic Systems – Founder
Very good comeback.

David Blumenthal – Department of HHS – National Coordinator for Health IT
That was one thing. The other thing we found was that a lot of the measures that were NQF approved were not electronically specified, and even if they were specified, they weren't tested, so we didn't have faith in them. So the final rule cut way back on the measures. We stopped. We eliminated the specialty specific measures or at least the categorization of measures. And we also cut in half the available measures, both for eligible providers and for hospitals. That created a challenge for us going forward, and the challenge was to make sure, to the extent possible, that lack of imagination, lack of forethought, and lack of technical preparation did not prevent us from adopting a more robust and useful meaningful set of measures for stage two and stage three.

We have, the department has put in process an alternative or a new sort of rapid turnaround effort to develop meaningful use quality measures. And we decided that the policy committee could offer very

important input to that by making recommendations about quality measures. The meaningful use workgroup did this part of the work in stage one, but it was working from a table that was already set. We were only looking at existing measures. While there was a lot of work to do, it wasn't nearly as heavy a list as thinking about new measures to develop and specifying them electronically and going through that much more detailed process.

We thought that it justified having a separate group. This group, which I'm chairing, David is co-chairing, has a terrific group of members. A couple other members of the committee are part of that group: Paul, Christine. It's, I think, doing really pioneering work trying to think about quality metrics in an electronic age. It's not something that we've done systematically before in government. And I think it's going to be very important for the Department of Health and Human Services as a whole, which is now developing a national quality strategy.

If you think about the future of quality measurement, it's hard not to imagine that or believe that it will be part and parcel of the electronic environment. So that the capabilities of electronic systems will determine and under … the quality reporting and quality improvement efforts of the future. So this is the beginning of a very important, new healthcare activity, quality measurement in the electronic age.

It's probably too much to ask the meaningful use workgroup to carry that burden, as well as laying out the framework for all the other aspects of meaningful use interoperability thresholds, new functionalities, all those other things. So I think that that's why we've turned to a separate working group, which we didn't do in the past. We're still talking about whether the quality measures workgroup will report into this group through the meaningful use workgroup or directly, but however we do it, it will have to, of course, we'll have to make it compatible and make sure that the aggregate burden for vendors and providers is not excessive in light of all the other things that are being requested in stage two.

Having said all that, I'm going to turn to David Lansky, who will actually report on what we've been discussing.

David Lansky – Pacific Business Group on Health – President & CEO
Thank you, David, and thank you for initiating this committee and leading it. We have, as David said, a wonderful group of people involved in this. I'm sorry this slide doesn't list all the affiliations, but we can obviously share that with you. But it's a very good cross section of people involved in the history of measurement work, as well as in the delivery systems, provider community, the IT community, and so on. So they've had a couple of good, initial conversations. What I can do today is share with you a preliminary sense of where we're headed, but we don't have answers to all of the questions I'm sure you'll ask about what the right answers are going to be in terms of measurement.

As David said, I think we're conscious of the fact this is not a wonky technical exercise. It's one that is germane to the health reform implications of our collective work. You all recall in the original HITECH Act, quality measurement was one of the things congress hoped would come out of the implementation of health IT, so this is, all the way to a statutory point of view, it's an important part of our charge collectively. And, as David just said, figuring out what does a new IT enabled healthcare environment permit us to do in assessing quality? It's fortunately a good problem to have.

So we are trying to think forward a little bit to 2013 and 2015 what do we expect to be the opportunity for the deployment of health IT to inform us about quality of care in America, and what dimensions and aspects of healthcare delivery that we care about will we now be able to measure? As David just said, the history of the measurement community, of course, wasn't focused on things they were not yet able to measure with an information infrastructure that wasn't yet there. So now we have that new opportunity. So I think it's really an exciting time, and a lot of people in the measurement world, the traditional measurement world are really cheering us on and seeing this is a chance to move a field that's been plugging away for 20 years with the old world. Can we jumpstart into some really new areas that are of vital importance?

The current state, as David just summarized does include a number of PQRI measures that are part of the CMS reporting program, and the … measures, which are part of the hospital-reporting program. One task in front of everyone is to retool some, call them, traditional measures to be reportable through IT technology, so that's already underway, and we're going to certainly take advantage of the retooling of measures for the IT environment. However, the new clinical health information that will be available in the IT environment is not yet informing the measurement work, so that's really our challenge to develop measures that are parsimonious, HIT sensitive, longitudinal, cover the various settings of care across settings and handoffs, address population health, and reduce the burden of care. I'm going to come back to this list of attributes in a second because I hope it's one that we will take a minute today and talk about a little bit.

For us, getting these attributes right is a really important cornerstone of the work. What is it? What are the characteristics of the measures that we're going to produce for your review? This is one shorthand way of summarizing that.

The charge to our workgroup is to produce recommendations on clinical quality measures for stage two and three with a focus on meaningful use of certified EHR technology. They should be applicable and appropriate to a broad range of providers. And the slide says each measure should use data that can be feasibly collected within the EHR. I don't think that's precisely right for what we want to do. That is, there may be data that assesses quality of care that does not come from, that is not collected by the EHR. For example, the patient experience measures we've talked about here for more than a year. That data may not come from within the EHR, but may be used to assess the EHR's impact. So I think we'll have to come back and fine-tune the wording here on this particular domain.

Our objectives are first to identify where are the priority domains that we should address when we're looking at quality. Then are there gaps in our current ability to assess those domains using electronic quality measures? One we identify the key measure concepts in each domain, which we've just begun to do, we will, as you'll see in a minute, try to decide where there are gaps and how do we fill those gaps in the very aggressive timeframe we're all aware of.

Once we are down that path of identifying the domains and the measures we want, we realize very quickly that there are crosscutting methodology programs that have not yet been solved that we're aware of or at least we've not accepted the solutions. So for example, as I just suggested, how do we capture data from patients, either about their health and their care, or about their evaluation of their care like patient experience measures. How and where do we capture those? And how does the way we capture those relate to the current infrastructure?

A simple example, you're all familiar with the CAP surveys that are used to assess hospital quality and health plan quality and sometimes physician quality. Well, those are based on an independent company going out and capturing samples of data from patients who may or may not have any access to health IT. Does that methodology and infrastructure work for our purposes? How do we capture data from patients who may or may not be served by an HIT enabled provider? We haven't talked about that yet. That's a methodology program that needs to be wrestled with.

Delta measures is a methodology question. We have a great interest in assessing the impact of care over time. So has someone's blood pressure improved from time one to time 2 in the space of 6 or 12 months, let's say? Maybe we can assess those two time points using the HIT enabled provider. How do we interpret that data? What is the measure of improvement or loss of functioning that we want to capture? We don't have an agreement about a methodology for assessing changes in quality of care or health outcome over time that we all know what the answer to that is.

We're talking about launching some tiger teams, our new term of our aggressive focused workgroups made up of a handful of subject matter experts and committee members who can help us come up with a working solution to those methodology problems. We're both identifying what are the problems we want to tackle that way, and then how do we configure a workgroup, a tiger team to go after them?

Now what we'd like to do then is having identified the domains of interest, the gaps in available measures, the kinds of measures we want, and the methodology challenges that need to get solved, we want to go out to the community of people who develop measures and do research and use measures and ask them for input on how we can solve these gaps, how we can address these gaps in a timely way. We're hoping that by this fall, we'll be able to put out an RFI to the measurement community asking for them to respond to this list of targets that I just summarized for you and give us some input very quickly.

Just to go back just for a second to the timeline issue because you'll have questions about it, our hope is by, I'll say, October and maybe November is more realistic, have that RFI process in play. By November, have done enough preliminary, or December, have done enough preliminary work to have what we call a superset of measures, that is the outer circumference of what we want to try to tackle. By next March, to have the measure priorities going back to Paul Egerman's point about converting our timelines to the spring. And by next May, have at least our committee work, have a final set of recommendations as to what they think can be addressed for stage two. We've essentially got nine months to try to march through this.

Deven McGraw – Center for Democracy & Technology – Director
…on the slide. I'm sorry, David. I didn't … can you repeat that …?

David Lansky – Pacific Business Group on Health – President & CEO
I hesitate to, but I will. To try to, by October/November, to have the RFI process available, and I'll ask Josh, Tom, David. Correct me if I'm wrong on the timeline, December to have a preliminary set of the superset of measures. This would be to Paul's earlier point, a preliminary signal to the market of which domains and categories we're interested in. By March, to have agreement on the measure of priorities that we want to really put forward into stage two. And by May, to have final recommendations on what the specifics would be.

Let me go through the rest. We'll come back. I'm sure the timeline issue will surface, and I probably don't have more to say, but I'd welcome everyone's input.

Going back to the attributes, I think this is an important area for the committee today to give us some input even though preliminary. We expect that the measures we recommend would be HIT sensitive, meaning these are quality measures, which we believe could be impacted by successful adoption of health IT. Secondly, that they be parsimonious, and this goes to the challenge that Gayle raised for us of addressing specialty measures.

On the one hand, we would like to find in a perfect world an elegant set of crosscutting measures that address virtually every provider without creating a lot of burden so that there's a small number of powerful and reflective measures of quality. On the other hand, we'd like to speak in the language and the skill set to each professional community that may be adopting health IT. How do we balance the potential for a huge library of measures that take a lot of time to develop and validate and collect and process versus the difficulty of finding an elegant and parsimonious set? That's a challenge.

Enables longitudinal measurement is one of these things that would have been very difficulty in the old world and is now enabled by technology. So we think that's an important challenge to take up. Measurement across settings of care speaks to the issues of episode, payment, ACOs, other means of integrating care across the continuum. How do we measure whether we are having, especially as we look at health reform if all the instruments of health reform are successful at improving longitudinal management of patients of care? And then, of course, ultimately, improving population health and having better measures of whether all these interventions are reducing the burden of illness for the community as a whole. Those are some of the criteria and perhaps in the discussion we can come back to the slide.

The domains of interest that have bubbled up, many of these came out of the work that George mentioned from the Gretzky Group, which was an ad hoc group that NQF launched to help think about the future requirements of measurement. I think Janet Corrigan and Floyd Eisenberg have briefed this committee in the past on some of the work they've been doing to move this along. These domains are

the ones we are currently working with, but they are preliminary, and we'd welcome your input on them. Patient and family engagement is a new area that we think the technology enables us to address better. Population health and public health, safety, care coordination, the broad area of appropriateness, including overuse and underuse, reducing disparities, and then addressing episodes of care.

What's not on this list that Gayle suggested earlier, the Gretzky Group at NQF did recommend that we look at what they called leading conditions, and they identified a dozen or so diagnoses or procedures that they thought were important and broadly of interest: breast cancer, COPD, depression, and so on. So looking at specific clinical areas like that and saying are there measurements, quality measures within each of those we should generate. We have not, as a committee, discussed whether or how to do that, but that's been proposed by the Gretzky Report.

I mentioned all these methodology issues, I think. Risk adjustment, I didn't mention. As we are interested in capturing more outcome measures for quality, we realize there's an important opportunity to do risk adjustment of those measures to reflect differences in how eligible professionals or hospitals might be receiving patients, so that may be another topic for a tiger team whether or how to risk adjust some of the quality measures or risk stratify them if that makes more sense.

I guess that's back to the agenda, so I think that covers most of our review of where we are today. As I say, we've only had a couple meetings. We'll be working very aggressively to move this agenda forward and try to have preliminary recommendations on October at a very high level of where we think we're going for this committee to consider.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
I guess I'd like to start the discussion by asking why we're doing this, why we're measuring. And I think we need to be clear on that in order to go down the right road, so here are the things that I think about in my mind. They're the kind of measures we establish in order to be able to compare different providers and see who is doing better and who is not doing better, and that could either be for people's internal use in order to improve their own systems, or for public disclosure. I think those things have very different kinds of implications in terms of how and what we're going to be thinking about measuring.

Then there's sort of the internal sort of quality improvement stuff, the stuff that's not meant to really compare people one to another, but basically to allow organizations to improve their own internal processes. That's another type of measurement, and it's sometimes done differently. Then there's the kind that says what role do the providers play within their community. And to the extent that they're impacting things in their community, are they impacting is a hospital impacting the emergency room use rates in their community or the number of people admitted with preventable conditions? Are providers capturing people longitudinally? Are they really serving as agents of primary and preventive care in their communities?

The reason I think that these are so different is because they really call out different types of concerns. So if you're really comparing providers one to another as a way of sort of thinking about public disclosure, you end up in a real abyss around risk adjustment, which really isn't a concern at all if you're asking people to collect data to do internal quality improvement. I don't really need to risk adjust. I want to try to achieve certain levels of performance within my organization.

Another implication is not just around sort of thinking about what the numerators are going to be here, but what are the denominators that we're looking at? When providers are looking to be compared one with another, one of the concerns that people always raise is these really aren't my patients. The issue of attribution, or these people don't really come back when I tell them to come back. The issue of whether or not you count somebody in the denominator when they've been in an office once or when they've only been in at least two times a year for at least three years, all of those issues around how we do this.

So I think, to get back to my original statement, it's really important for us to understand and to call out what it is we're doing the measurement for. And to be clear, I would take a position that we need to focus in the broadest possible way to think about population health now, so we don't obsess about the issues of comparing providers, one to another. I think there's enough data out there that patients don't use these publicly disclosed statistics about hospitals and other things to the extent that we would think that they would in terms of picking providers. And I think we're going to get into a mess around risk adjustment that's never been solved successfully. I think what we really should be doing is calling out the idea that people are collecting data for internal quality improvement and trying to keep the denominators as broad as possible, so we're also calling out the issue that we're interested in people looking at the broadest population of folks that have come to their centers, and to do that, you've got to get away from, I think, saying that what we're really doing is capturing all this information in order to disclose it publicly and have people be able to compare themselves or compare each other in terms of outcomes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
I'd like to kind of piggyback on what Neil has said, and I couldn't agree with him more in what is the charge of our committee, what is the purpose of our committee, and what we were statutorily charged to do. Are we going into a whole endeavor that truly there's a community out there that has done this for the last 20 years in establishing quality measures, and that's a real scientific thing that has to be done appropriately. This is the full employment act for our whole staff here. Poor Judy is going to be overburdened, I can think, with all the, you know, what I envision to do this appropriately, I think we have to be extremely cautious in how we do this, and that we don't go off on a tangent and go into something that we first of all don't have the statutory authority to do. And, secondly, that we don't have the 20 years of expertise that is out there to do it.

I understand why we want to do something. Why we want quality measures that are going to show that people are effectively and meaningfully using electronic health records. And I absolutely applaud you that we need to really go into and make sure that we bring our specialties into the whole mix of electronic health records, and we have – they have the ability to use them appropriately and to show, demonstrate that they use them meaningfully. But I'm somewhat concerned in the direction that this could take us and where we're going with it and the ultimate reason that we're going there, and what reason are we measuring for?

David Blumenthal – Department of HHS – National Coordinator for Health IT
If I could just respond to that briefly, and this particular committee has limited capacity and limited time, and it may or may not be able to devote sufficient time to this activity so that we'll all be comfortable with what comes up. But the fact that the field is going in this direction, I think, is indisputable. The Affordable Care Act requires the secretary to develop a quality strategy for the country as a whole. There are a lot of provisions of the law that do focus on improving quality measurement and, in fact, the statute that empowers the HITECH Act calls out quality reporting as a key element of meaningful use.

I think that we have some responsibility to do our best. The committee does not have to do that. This group does not have to do that if it doesn't feel it's capable or ready or appropriate for it. But it is an opportunity for you to have an affect on what the rest of the department is doing. Judy?

Judy Faulkner – Epic Systems – Founder
I'm following up a little bit on what's been said so far. I am nervous that the government is going to really get into the electronic health record design business. And so some of my experience has been that if Group A respected, distinguished healthcare organizations creates some stuff for the electronic health record how they like it, and you take it to Group B, Group B doesn't like it. And then Group C doesn't like what Group B or Group A did very often. And they will say, we respectfully appreciate how they do it. That's not how we do it. My worry is, as I see these things here, that we're becoming Group A and expecting groups B, C, and D to like what we did. A lot of the work effort that goes into what I think is really interesting, which is not necessarily writing things new, but because there are nuances in the

differences that are significant enough that in order to meet the rules, you still have to do it. There's a lot of work to be done.

Now looking a little bit into how much work that is, the information I'm getting is if have a vendor in reasonably good shape, you're talking about maybe 5,000, 6,000, 7,000 hours of work just to go from the final rule to stage one, and keep in mind that it's not just make changes to your software. It's going back and retrofitting your users who have previous versions who can't change in time, but are very strong about we have to have you retrofit our software, so we can stay on the same version without having to go through an organization wide change. So that's a lot of time too.

There's time for development testing and retrofitting, and I think that you're going to get into many thousands of hours of work, so my feeling would be, be really careful about these committees not becoming the design committees for what the country will do with electronic health record, and try to keep it more general. And I like what Neil said about different groups do it differently. How do we do it so that they can do it in their own way and have it work rather than we're very specific about how it should be?

David Blumenthal – Department of HHS – National Coordinator for Health IT
…comment?

David Lansky – Pacific Business Group on Health – President & CEO
Sure. Judy, I think it's really helpful for you and colleagues to give us feedback about the challenge and difficulty of the reengineering that may be implied by anything we start pursuing.

Judy Faulkner – Epic Systems – Founder
I can give you more ….

David Lansky – Pacific Business Group on Health – President & CEO
Yes. We should really welcome that and find a way to capture it. But I also want to figure out. I think part of what we see as our charge is to reflect, as with all of our meaningful use work, that the use of public funds to create an incentive for change in healthcare data management and use, one of the statutory responsibilities is to enable quality measurement that's meaningful. There's a lot of criticism in the quality measurement field that a lot of what we do now is not meaningful, and there's a hope. Measure that matters is a phrase people throw around in this world that we can find that perhaps somewhere in these domains are some measures that matter, and it's very valuable to work with the vendors and the providers to find ways of capturing the information that would really matter, both for the various purposes that Neil described, and I take Neil's caution that we can't solve all those needs. But I guess I'd hope that we would find a way to work with the vendor community to be very efficient in whatever alterations are needed in the underlying software platform and that the measurement calculation and so on may be done through an external activity, not necessarily through deployment through all the different sites if the underlying data is being captured in an acceptable way.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
I think there's tremendous value in what we're talking about here. Again, appropriately focused. If it's so broad that we're reacting to 100 different approaches, it would be painful. And I only had one comment on the attributes slide, and it hit some of the points that were being talked about, but I think an attribute of locally useful would be good in that we're not just producing statistics, produce statistics, but that it's got value there locally. That was it.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thanks, Marc. Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I'll try to aggregate and provide a summary of win/win. I think, in the context of HITECH, in the context of this committee, there's quality improvement, and there's public reporting. They're very different, as this group well knows, and there are a lot of groups that struggle with that different, and primarily the difference because they're a different purpose, which was Neil's original point.

This committee is on the road towards improving health outcomes for individuals in the population. Our tool is the use of EHRs. It seems like the proximate objective that we can strive for is to develop quality measures that can help us use the tool. That's very much, I think, aligned with what Neil said, and not as much to concern ourselves with the public reporting aspects. That has a much bigger context and it just has a much bigger impact and has a different cultural implication than the QI roles.

From the HITECH perspective, trying to build and effectively use tools that improve quality sort of locally, quality measures that contribute to QI, I think, is our more immediate target. And then it can go on to, as input to the other organizations that are working on the public reporting side. I don't know how well I've articulated that, but I think there's a real difference where we can have a win on the road towards improving population outcomes.

I had a couple other comments in terms of your slides. One is the domain. Is there any reason we wouldn't want to stick with the same domains that meaningful use already has in this framework rather than expand it just to keep alignment together and keep the seamless transition, however it works its way through, to the final recommendations. It just seems like it would just be easier that way. And the final point is the RFI timeline. You have May as your endpoint. Considering the discussion we had earlier about April, is there a way to get that to be in synch with the April-ish kind of timeline that meaningful use is trying to meet? If you could precede that, so whether it's April or as much before April as possible, that would be useful input just so that the combined package can go forward to ONC.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Michael?

Michael Weiner – Defense Health Information Management System – CMO
Yes. I agree with the points Neil makes, and Paul restated them. But I think it's clear to me that if we do focus on measures that are used for institutional quality improvement, that once those data are available, they will be compared across institutions, and people will find a way to role them up and do, if you will, these comparisons. So I agree the focus should be there, but the committee has to realize that it's likely that these data are powerful. They may be imperfect for doing the kinds of things Neil wants to do, but I think the committee should be aware, they might be used and have that in the back of their mind as they think about the measures.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
Just to make one more point, I think one of the concerns I have is that if you develop measures that are broadly set out, and they're not particularly relevant to improvement activities in a particular organization, you divert energy from those improvement activities. This isn't like an additive game that you can do all of this stuff at the same time. So once you set out a set of measures that say these are there to compare people, what you end up with are organizations that function around those measures, which may not necessarily be relevant to that particular population or to the kind of processes that that organization has in place. And that exactly describes what Judy was pointing out is that we download these measures from other organizations, but they never function exactly the way you can put them to use in your own organization, either because of the resources that you have or the types of patients you're serving or any other number of things of other objectives that you have going on. And so I think it is really important.

I do appreciate the fact that we do need to report this stuff. But it forces me into this harder question, which is, how do you take this stuff that we were trying to signal to people to do to improve the quality in their organizations and report it publicly without having to have it be all the same because otherwise that

sameness creates a distraction from people actually being able to do improvement work in their own organizations in many cases. Not in all cases, but in many cases.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Just a little context: The quality measures that are incorporated into the meaningful use framework are quality measures that, by definition, are reported. So we can do creative work around metrics that are useful for quality improvement, but they don't, they're not going to find their way into the meaningful use framework unless we require that they be reported. So I think that that may be a reason to be more parsimonious.

But it also is an opportunity to be useful. Reporting has an affect. It's not an affect on consumers. It's an affect on providers. And no one wants to be in the bottom 10% of the quality distribution. And we see when good data are reported, providers respond, and quality improves. So there is value in this reporting process. It's not simply make work. It is incumbent on us to be HIT sensitive, parsimonious, and develop quality measures for quality reporting. But people with electronic health records are using them to develop hundreds of internal measures for quality improvement. These are not inconsistent activities. Christine?

Christine Bechtel – National Partnership for Women & Families – VP
Let me … followup question on that to clarify. When you talk about the reporting process, you mean the reporting to CMS, but we're not talking about public reporting of meaningful use. I think that's an important distinction because, I think, Neil, you're right. If you talk about public reporting, it's a slew of issues. It's a little bit of a mess, although I personally would love to see them all publicly reported, but that's' another battle.

What I would say is it just strikes me that part of what we're struggling with, we're not talking here because the workgroup is just getting underway about the specific measures and whether they're the right ones necessarily or not. I think the challenge that that's posing for me in our conversation today is that we're talking about measures in the abstract, and they're doubly abstract because they're in the absence of any kind of goals that we're aligning to. So I'd rather have a conversation about whether something like reducing hospital readmissions or reducing adverse drug events, are those the most, if you will, meaningful measures of meaningful use? So the measures that we're looking at should be designed to assess whether taxpayer money is actually going to the right place and being used in the right way to achieve real improvements for patients and families.

I know that we had this conversation before, and I can hear David and Paul, but I'm going to say that, and I'll keep saying this. NPP, we've used their framework. We've engaged them in looking at these measures. They've got goals, and I think that we need to look at those goals. As a committee, we can recommend whatever we want to recommend, and you are free to reject it. However, I think they have some really important goals around care coordination, around readmissions, around patient safety, around patient engagement that if we can begin to align quality measures to the goals they're achieving, number one, that just seems to me like the right answer.

But number two, partly that's because the conversation I'm hearing in the public domain is all about bits and bytes and technology and money, and that isn't what it should be about. It should really be about what are we trying to use the bits and bytes and money to do here. I think that's what we've been struggling with for a long time, so I just want to again say, I think we ought to relook at the NPP goals and align the measures towards them.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
I'd just like to point out one opportunity that perhaps we have, and with the resources that the ONC does have is that there are national groups that are actually, that as you say, that do construct these reporting, that do construct quality measures. And perhaps this is an opportunity, a granting opportunity to assist

some of these groups in developing EHR specific quality reporting measures. Perhaps we need to partner with other groups that are out there to help develop the kinds of measures that perhaps when we get to stage three would be appropriate because it's a whole timeframe that goes into constructing these appropriate measures. As we all know, those of us involved in healthcare for a long period of time, that that takes a process to go through, and this committee doesn't have the time or the resources to do that.

So Judy is already working 24 hours a day, so we don't have time. Our tiger teams are totally involved. However, there are groups that do this, and that this was an opportunity to perhaps look for those kinds of measures and have other groups help determine or construct new measures that are specific to EHR.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Judy, did you want to talk again? I'm sorry. Go ahead, Judy.

Judy Faulkner – Epic Systems – Founder
One of the things I wanted to mention was that it's very hard to prioritize when you're looking at one item. And I think that's one of the problems we're having here. When we just look at quality measures, or we just even look at meaningful use, by even trying to figure out what is really important for our country with those, we are not doing at the same time is understanding how much a vendor's percent of time is taken, and then what else does not get done that later one we'll say, "Wow. Did we adversely affect the development of EHRs with regard to patient safety, ease of use, functionality, patient interaction?" And all those things that had we known what they were there, might have been on the list, but we're not realizing the affect. And I think what we need to do, and I've been trying to ask folks back at the office, canvas the whole EHR community to figure out what are the answers to what happened when the first rules came out.

Now I know that we've thought, we matched them. No more work until the last rules came out, which turns out that there may be up to 3,000 hours of work, which is significant. What does that mean doesn't get done? And then are we, would we regret it later? I think that analysis has to be done of what percent time of a vendor does this take, and then what didn't get done that should have been done. Excuse me?

M
Or a provider.

Judy Faulkner – Epic Systems – Founder
Or a provider as well, yes. So there's nothing wrong with these. It's just that prioritizing without seeing the full range of everything else that has to be done can really give you wrong answers.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Maybe I just want to clarify the phrase, publicly reported because, I think, in the HITECH context, we're talking about reported to CMS for the purpose of assessing meaningful use of HIT, not for public reporting, judgment, and comparison. And I think this gets to the heart of the matter. I think the quality, the measures that are defined for internal quality improvement have a different goal and end up having a different affect than the measures defined for public reporting.

Oftentimes the sole reason for quality improvement measures is to sort of rise to the top, to constantly better individuals and the entire performance of the organization. Too often, I think, the public reported, the definitions of publicly reported measures create a race to the bottom kind of lowest common denominator effect where everyone is trying to maximize how everybody can get an A. And they have very different goals, and they have very different affects, which is why I think if this committee, if the policy

committee directs its efforts towards how do we assess if people report that they can use these tools to improve their quality, that may be closer to our end goal than the publicly reported comparison measures.

That's the distinction at least I'm trying to propose, and I think it's consistent with what Neil was saying. And it has different implications even to the vendor world. It clearly reduces the workload for getting quality measures, if we talk about the more QI, the internally used measures to demonstrate you've meaningfully used the technology because the work and Gayle points out that all these organizations working on the publicly reported side have to worry about the political context and all of the cultural pushback that occurs.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
So maybe this is a good reason, David, to go back to one of your original comments, which is, where does the group report to. Maybe the context is really different. If it reports to meaningful use, then it's really only concerned about measurement in relationship to meet meaningful use. But I guess my recommendation would be that it report to the whole committee because it's really the measurement discussion that we need to have at the policy committee level, I think, is broader than that, which is, how is the technology used to improve the quality of care that's given to people across the country, and that meaningful use is only one piece of that, and that doesn't become the whole discussion, but it becomes one part of that discussion.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well, whether or not it reports through meaningful use here or directly, its recommendations will come here, so the reason for engaging this group in this discussion is because of the meaningful use requirement. The value and the requirement for this group's involvement stems from the fact that there is $27 billion on the way to providers in response to requirements that you all are advising the federal government on creating. And you can, therefore, have an impact on the way electronic health records evolve and the way practice evolves through your recommendations about meaningful use.

Your recommendations about quality measurement in general will be of interest, but will have far less direct and obvious impact. They may be influential, but the opportunity to actually disseminate and put in use the measures is almost unparalleled in terms of the meaningful use framework. So I think, as a prioritizing process that we can all think of lots of other things that are valuable to do, the thing that we ought to be spending our time thinking about is what measures that meet these criteria belong in the meaningful use discussion and meaningful use framework. And so I think it gets back, I think, to Christine's comment about setting goals, and Neil's what's the purpose. What are we trying to accomplish through meaningful use? And how can the measurement of quality contribute to that? Charles?

Charles Kennedy – WellPoint – VP for Health IT
Yes. I'd like to offer perhaps putting some of these comments within the context of healthcare reform. Within the health plan industry, there's a lot of concern about cost, as usual, but I think that with healthcare reform, and other drivers, you're going to see new, innovative products that try to deal with cost in new ways such as, well, may not new, but narrow networks that we've seen before. And I personally worry a lot about the potential impact on quality, right? I mean, we want cost efficiency. We don't necessarily want cheap care.

And without this electronic quality measurement process, I think we have a real risk of not getting the outcome we expect. So while I appreciate the concern about the public disclosure and the physician attribution issues and the risk adjustment issues, which are all nightmares, we do need to find some way—perhaps it's outside of the purview of this committee—but to make some of this information sharable. Otherwise I don't know what our defense is against ending up in an environment where quality takes a back seat.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Lots of great comments. More to come, I'm sure. I'm sure this committee will rise to the occasion. Thanks, David. Thanks to the committee and all the commenters. I think we're ready now to talk about governance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good morning. Can you hear me?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, we can, John.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Great. I'm sorry I couldn't be there in person, but as you will hear later, I will be at the next meeting. After the conversation I was just listening to, it's nice to present a topic that is simple and non-controversial. So we're going to talk a little bit about the charge that's presented to our committee that the HITECH directed that the National Coordinator establish a governance mechanism for the Nationwide Health Information Network. As you all know, that name is in the process of being reconfigured.

This proposed rulemaking would identify government mechanisms that engender trust, assure effectiveness meet or exceed consumer expectations, promote and facilitate use of national health information network. As the committee has begun to initiate the process of discussion, we think that there are some critical components to that that we're going to be looking at. The first is that, as you can see in the next slide, our charge is to draft a set of recommendations on the scope and process of governance for the Nationwide Health Information Network through measures to insure accountability and oversight.

As we've had our discussion, we're going to do most of our focusing on those things over which the Office of the National Coordinator has a role. We may identify other actors in the field of governance, and we also want to make sure that when we do identify that, that we identify a certain level of granularity so that we're not getting into what a standard should be. Perhaps we may look at who should be setting the standard, or we may even, at a higher level, look at who ought to be determining who sets the standard.

Our overarching concern on this is that we want to do two things with this process. First is that we want a governance system that engenders trust: Trust in the provider, trust in the patient, both of whom are concerned to make sure that privacy is adhered to and protected throughout the network, and trust in those who are exchanging data. And the second overarching concern that we have is about interoperability. And that is that we want exchange to happen, and it is through exchange that the right information is available at the right time so that the right decisions can be made in conversations between patients and their caregivers. Looking at this approach to governance, we also want to take a lien approach, enough to generate trust and facilitate interoperability without stifling innovation, and so that's an area that we will be looking at, as we go through our process.

Next slide, this slide includes the members of the workgroup, all of whom agreed over a very short period of time to take a look at the issue of governance, and we're doing this not doing this just from whole cloth. In fact, we're looking at some of the work that has been done before by NHIC, by looking at the DURSA, and other governance documents that had been developed as we've moved forward in trying to enhance the ability to exchange health information to improve the quality and effectiveness of care.

Next slide, so our committee has a certain set of deliverables. We're going to be having a hearing, which I'm going to talk about in a second on September 28th. We will be coming up with initial recommendations, which will be presented to your committee on October 20th, and final recommendations to be presented on November 19th. Subsequent to our presentation to your committee, the policy committee, there will be a discussion and recommendations by the policy committee to the ONC, and then, subsequently, they will be issuing a notice of proposed rulemaking, and our workgroup will then conduct hearings and submit comments on those proposed rules based upon the input we get from the broader health information technology community and the patients and organizations that represent them.

Just to give you an idea of the timeline, it's a very quick timeline for the first phase of our work, as has been much of this activity, but we think that we have a very good workgroup that will rise to this challenge. The next slide gives you a little bit of a feel for what this governance hearing will be. It has evolved a little bit since this slide has developed, so let me walk you through that.

Our hearing on the 28th will have the first panel that will, as on this slide, will look at governance models in other domains, for instance in the business world, e-commerce, those kinds of other domains that we can see how governance is addressed to engender trust and encourage interoperability. The second panel and the third panel, as on the slide, will be looking at implementers of exchange, and we're going to be looking at this in two ways. One, the first panel will be looking at the experience of those who are implementing of exchange in what are currently now nascent HIEs and those with a little bit more experience. And then the second panel, we're going to be looking at those who are doing exchange in venues that are separate or involve a number of HIEs. I can't give you any specifics right now. We have all the letters of invitation are out, so we are still putting together the names of individuals who will be on this panel.

The last panel, we've sort of combined four and five. We'll be looking at existing governance authorities, including some that have direct authority over health information exchange and those who have general authority over how exchange may occur, and looking at these at the state and federal level. As I mentioned, this is a workgroup that was actually just had our first meeting. I think it was maybe a week before last, and we hope to get this charge accomplished within the timeframes. I'll be reporting back to you on the 19th of October for our preliminary findings. I'm sorry, the 20th of October with our preliminary findings, again on the 19th with our final recommendations. I'd be happy to answer any questions.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, John. Questions? Gayle?

Gayle Harrell – Florida – Former State Legislator
When we're talking about governance, are we talking about governance for NHIN? Are we talking about establishing parameters for governance of RHIOs, of state entities? What direction are you taking, and do we have the authority to establish governance models for state entities or local entities?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The committee is actually looking at all those parameters, but we're trying to scope this down to look at those areas with the most focus where there is clear authority of the Office of the National Coordinator to play a role. There are already some state entities that have established some criteria for state exchange. What we think we need to do is to be able to create an environment where we produce the least amount of barriers for exchange. Yet, at the same time, enable, and someone who is in Eureka, California, to feel comfortable and have trust in doing exchange with someone who may be in Portland, Maine.

Gayle Harrell – Florida – Former State Legislator
I'd like to do a little follow up on that. I think certainly we need to – the most important thing we need to do is make sure that we establish that trust mechanism, and people in Eureka are comfortable in exchanging in Stuart, Florida. However, that is extremely important, as you all have heard me say again and again, that is the most important thing we have to do any time we have exchange is to have that trust. And the privacy and security elements are paramount.

However, we also have to recognize that states do have authority in a lot of these areas and that do we have any – what authority do we have to mandate or require that states meet minimal requirements for certain elements of governance? Certainly that accountability and enforcement and oversight elements are so paramount in making sure that that trust is there. Perhaps Dr. Blumenthal could answer that a little bit better. What's our statutory authority to do that?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I was going to toss it to him.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, John. My law degree is fresh.

Gayle Harrell – Florida – Former State Legislator
Yes … preemption. At what point does the federal government preempt state law?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

W
(Inaudible.)

David Blumenthal – Department of HHS – National Coordinator for Health IT
There are many ways in which— I was a political science major, so ….

Gayle Harrell – Florida – Former State Legislator
Wait a minute. Don't forget that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
There are many ways in which ONC and the federal government generally can incent states or other entities or individuals to participate in certain ways. This really will end up, to some degree, being a matter of collaborative participation as much as any coercive effort. So we have the authority to create the governance for something called the Nationwide Health Information Network. Right now, there are a dozen or so entities, including most major healthcare agencies of the federal government, that are participating in an organization called the Nationwide Health Information Exchange capability. And it is, they very much want guidance on how they should govern themselves.

There are another X number of organizations, including a bunch of states, that want to join them. And because they realize, as I'm sure the state of Florida would realize, that being able to exchange information between states is valuable for their citizens. And for a state like Florida with its movement of people back and forth in the seasons, it would be a great advantage to the state to be able to tell its citizens that they can spend the summer in Vermont and the winter in Florida, and have continuous healthcare. So I think, if we can create a system that people trust and that works, it will attract a lot of participation. We won't need to mandate participation. It will be an attractant rather than a mandatory requirement.

Gayle Harrell – Florida – Former State Legislator
Do you anticipate setting minimum standards that in order to participate you must meet?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. I think that's part of the trust fabric is that when you are exchanging information that the recipient and the sender have some understanding about how the information will be treated. There may still be opportunities for varying consent requirements at the point of entry, and we still have to work through that, and that's part of what we're asking John and his group to help us think through.

One can go the next step to say we are giving grant funding to states, and these are cooperative agreements, and we can discuss with them in the context of that cooperative agreement how they run their plans and organize their plans, and we're going to be doing that. And Medicaid also is giving substantial amounts of money to states for health information technology with a 90% federal match for making Medicaid, making it possible for Medicaid programs to participate in health information systems, so that's another point of influence. I think there's a framework of kind of around which we can negotiate, but I think most of what we're going to be trying to do is create an opportunity that folks find irresistible. Yes, Paul?

Paul Egerman – Software Entrepreneur

Yes. First, John, thank you for a parsimonious group of slides. What I'd like to comment is I go back to the original charge, which talked about governance of the Nationwide Health Information Network. To me, the real issue, well, what is the Nationwide Health Information Network that we're governing? It partially speaks to the issue that Gayle raised, and the way I look at the Nationwide Health Information Network, the way I think we're defining it; it's sort of like a collection of standards and processes.

Governance is really all about adherence to the standards. And, fundamentally, it's a huge governance issue that always exists in something like this is what do you do if somebody doesn't play by the rules, isn't doing what they're supposed to be doing? And it just strikes me that there are a number of policy levers that are available to ONC. One of them that is very powerful would be the ability to revoke certification from a vendor if something isn't going correctly according to standards or according to privacy. The other one is the ability to deal with grants or funding activities from ONC to the state organizations.

But it still ultimately is going to be, in my opinion, about how do you enforce adherence to whatever standards are established? That's really what the NHIN is all about is a collection of standards, unless I'm missing something. So it's not really about what is the Florida RHIO doing. It's really what are the standards.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Gayle?

Gayle Harrell – Florida – Former State Legislator
What enforcement capability is there? The bottom line is, when you have averment behavior, how do you enforce the standard?

Paul Egerman – Software Entrepreneur
…payer?

Gayle Harrell – Florida – Former State Legislator
Once you have an exchange established, and the incentives are in place, the incentives are paid, where do you enforce the rules? There are people who abridge the rules. And, unfortunately, we make laws for the few percent of people who do abridge the rules and break the rules. That's why we have law. So who is the enforcement agency at the end of the day?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Deven, are you going to answer that question? You don't have to. David?

Deven McGraw – Center for Democracy & Technology – Director
Well, I mean, it seems like you – I mean, there isn't a magic bullet here. I mean, I think it's the constellation of enforcement tools that have already been thrown on the table. The spending conditions and the various programs being one, meaningful use and certification criteria being another. But the third, which is where I hope the governance workgroup will spend a fair amount of time, and it sure looks like that's where they're headed, is on the issue of consent, things that you voluntarily ascribe to for which the penalty is not being able to participate and how meaningful that is. Well, in some part depend on the level of a public acceptance of the criteria and the infrastructure that's put on the table.

I mean, what is the penalty, for example, for not being part of a professional association? It may not be that great depending on the level of credibility that that association has. I have always seen, and my hope for this was that there'd be some work done on both what the sort of more heavy duty enforcement tools are that are available, not to suggest that those aren't important and that that's not a valuable part of the process, but this sort of third prong of creating partnership type infrastructure that people voluntarily ascribe to, and there is value to that.

Gayle Harrell – Florida – Former State Legislator

I absolutely agree with you, Deven, if I may continue. The question really is, when you're talking about a person's privacy and security of their electronic health records, this is so valuable that we have to get the governance right. We have to make sure that there are protection mechanisms out there at the end of the day for that few percent of people who are not going to play by the rules. Most cases in professional associations, everybody is there to play by the rules.

There are few people who are not going to play by the rules. And we have to make sure that there are penalties involved, that you make it difficult for people who are not going to play by the rules. And I don't know where we have the authority or this committee has the authority to do that. Certain the Office of Civil Rights can play in this to some degree, I would think, but there needs to be a whole conversation on where the authority is to, at the end of the day, protect the privacy and security of that record that is exchanged. When you get into the risk, that's where the risk is.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me perhaps jump in here and say that one of the things that this workgroup will be doing is we'll coordinate our efforts and looking for activities from the privacy and security workgroup that is actively engaged right now. But I think we have to recognize, and I chaired the National Committee for Vital and Health Statistics when we were implementing HIPAA in the late 1990's that there is a body of law and significant penalties that are in place related to breaches of privacy. But that what we learned when we were conducting hearings and working and advising the department on putting together those regulations was that most of what needed to be done, needed to be done in the policies and procedures that were in place to insure that privacy was protected.

That's really where I think the governance comes into play so that if my exchange is actively adhering to the best practices that protect privacy and security, I want to know that the exchange I'm sharing data with is also doing that. And that's where trust is engendered, and that's really what we're looking at within governance. And that if we all agreed that we're going to adhere to certain standards, then I think the role falls to the entity that we will be making a recommendation about. I don't think we've gotten that far yet, whose job it is to certify that an exchange or an entity sharing data on this level, at a national level, is in fact adhering to what we know as best practices and the policies for privacy and security.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO
Thanks, John, for all your work on this. I think, building on the conversation, not only is there the enforcement for potential violations, some of which could be remedied with legal action, some with other kinds of activity. But there's the initial setting of standards, and the deployment of those standards, and the monitoring of compliance with those standards, to Paul's point, and then the enforcement if there are some breaches or problems with that where it's not self-enforcing. And it strikes me that there are – the reason I mention this is in the context of the information exchange workgroup, which I'll report on with Micky later today, we're already working on the provider directory recommendations. And in that work, the issue comes up quickly of which providers are listed in a directory and under what criteria, and when might they be de-listed?

I say that in the context of there being a number of, as Deven said, enforcement mechanisms that are not all legal and not all obvious. And I think part of the challenge for the workgroup, John's workgroup is to build a framework that addresses both the most sort of rigorous and formal means of enforcement and the less, all the way down to the least rigorous, maybe reputational means of enforcement. And then, in the middle, there are some other tools like whether one is listed in the provider directory with an asterisk next to their name that the trust level is not something. You can imagine a lot of ways of technical implementation that would address this question.

But I think the governance workgroup will have to think about technical infrastructure solutions, policy solutions, and contractual and agreement-based solutions that where governance – and the last point I want to make is that where governance happens is not yet clear, so that some things may be subject to

national uniformity, and there needs to be a national infrastructure for deploying and enforcing those standards. Some times may not need to be nationally uniform, but may need to be uniform in a market or in a region or state. And I think, coming up, John, with a table or a framework that says which things need to be governed at which level of jurisdiction, if you like, and with what level of formality would be a really important service to the rest of the work that some of our other subgroups are doing.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The challenge I think we have is even though there is a body of work out there, for example, HIPAA, as applied to covered entities, we know that the compliance with that is variable, and that's where the challenge is, and that's where the trust or lack of trust occurs. So in a sense, once you cross organizational boundaries, you're going to be faced with the lowest common denominator. By the work that Deven's privacy and security group did, well, actually it was in the meaningful use. The original proposal was that in order to help reinforce compliance with HIPAA security rules, there was a caveat that said, look, your payment will be withheld until you met the existing standard, but that did not make it to the final rule. But that's kind of the challenge that we face because we found out that many organizations do not even meet the current HIPAA security rules in terms of meeting the addressable rules. The question is, how can we meet that challenge and assure people that even if there are rules, existing regulations or laws, are all the organizations that are going to receive data from our organization going to meet those, and how do we insure that that happens?

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think you guys have earned lunch, so we're going to adjourn for 45 minutes, back at 12:45. See you then.

(Break for Lunch)

Judy Sparrow – Office of the National Coordinator – Executive Director
Welcome back, everybody. We're about ready to start the meeting if you could please take your seats. The HIT Policy Committee will now resume, and I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So we're, I see poor David Lansky is doing double duty today, but I don't know if Micky is on the phone. Micky, are you there?

Judy Sparrow – Office of the National Coordinator – Executive Director
…David is aware.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Okay. Well, David, you get another crack at us.

David Lansky – Pacific Business Group on Health – President & CEO
Micky, when he joins, will add a lot, is what I can say. But let me report to you all on, again, the first couple of meetings of a reorganized workgroup that is one that you all know the work that the information exchange group has presented in the past around laboratory and other information sharing requirements. And, as you know at the last meeting, I think we approved a somewhat refocusing of the work of the information exchange workgroup. So we've had a couple of very productive meetings and have launched some taskforces, and I'll just summarize, until Micky joins us, where we are in that process.

Here's a roster of how is involved in the reconstituted workgroup. I think one notable thing you'll see is additional state representation. I think we've found that it's very valuable at this stage of the rollout of the cooperative agreements in particular to have more, a number of state coordinators involved with this workgroup giving us feedback from the field, if you like, as to what's actually, what are the pressing issues that they're facing, as they try to build out their state HIE program. So having them at the table has

already been very informative, including representation you can see from Medicaid programs, as well as state coordinators.

The charge of the IE workgroup, to refresh your memory, is to look for the breakthrough areas where there may be obstacles that prevent providers and states from enabling health information exchange. We've already – focusing on the clinical transactions that are listed as part of stage one requirements. And we're also seeing that the new programs like Beacon and others are bringing up new issues for our attention. We also, as I just suggested, see if one of our jobs is being to bring the state concerns to our table here and try to support the state programs in being successful where there are issues across multiple states' attention.

Now we've created two taskforces, and both of these, I think, arise from feedback from the states. So the first one mentioned on this slide is the provider directory taskforce, which Jonah Frohlich from California and Walter Suarez from Kaiser have nicely agreed to cochair, and they really grabbed the reins and are moving very quickly into some substance that I'll summarize for you. And again, you see a list of some of the people involved in this taskforce.

The problem that the provider analyst mentioned that the second taskforce is called the public health taskforce, which we'll come to in a moment. Both of those topics, the provider directory issue and the public health issue, are ones that the states have told us they need help with very, very quickly. In the case of the provider directory issue, many of the state cooperative agreements are undertaking to stand up some kind of provider directory function, and they're trying to do that in the next few months literally. Of course, we're all sensitive to the idea that we don't want one state to build a provider directory that can't be accessed by another state because there hasn't been sufficient attention to standards and cooperative definitions and policy rules. So we feel a lot of time pressure to come up with some guidance around the provider directory solution set.

The problem we're trying to solve, we're focusing on these certain transactions, most of which need a provider directory to facilitate the message traffic. While there are multiple ways these functions we performed in the market, they all have to correctly identify providers and manage addressing of providers. I will say parenthetically that we know that there's also an authentication issue, which as of our call yesterday, we are trying to put in parallel, but separate path, with the simple addressing issue.

We realize there'll be a number of uses beyond the immediate exchange transactions that are required for meaningful use, such as public health, health plan traffic, and so on. And I would just say that while we are not immediately going to try to solve all those problems and provider addressing for all those users, we do realize that there's a business case issue to be addressed. That is, the HIEs, and I can speak for California where I'm more involved, realize that after the initial funding from ONC goes away, they will need a sustainable business model to manage whatever core functions the states decide to stand up.

It may be that something in this provider directory service becomes part of a business function of continuing value for the state HIE, which means that now we have to give some forethought to whether there's a public health use, a health plan use, or another use of this provider addressing capability. And if there is, make sure we design for that possibility so we haven't built a dead end. The lack of universal approach to provider directories will be a barrier to progress and a missed opportunity, which comes to this multiple streams of funding question. And, of course, our task is what can federal and state governments do to catalyze a market enabling provider directory approach that serves the immediate needs of directed exchange, as required for stage one, but also is a platform for future needs.

Now this is a long list of topics that are surfacing from our first discussions as a committee, and we certainly won't talk about them all today, but I just want you to have a feeling for the scope of when we say provider directory, it sounds like opening the white pages. But actually there are a lot of issues that we realize we will have to consider. We may not address all of these. What types of individuals or entities should be in the directory? We've had a very lively discussion of whether we're talking about

legal entities or about individual clinicians and how we address that, and what the requirements are going to be.

What type of information on each entity that's listed in the provider directory? What standards are needed that are uniform nationally versus to be managed by a local directory? The architecture, is this a single, national, unitary directory, or is it a federation of directories that already exist or some hybrid of the two? How do we assure that the data is good in these directories? How do we maintain the accuracy or what standards for accuracy do we have in these registry entries? Again, is that something that's nationally required in standard, or is it left to a local jurisdiction to determine? How do users access the information? How is the quality of information maintained? How is all this paid for? And then what is the trust framework that guides collaboration across entities so that we do know that if I make a query for Massachusetts to California, I have confidence that the entries I'm retrieving are sound and that they are representing business partners correctly, who I may not have any other relationship with.

It's a lot of issues ranging from technical, policy, and so on, which we're going to begin to delve into in a hearing on September 30th, as suggested by this next slide. So our plan is to do, as a committee, to flush out this list of issues, and then to hold a hearing in a couple weeks with a number of those who are either users of these provider directories today or already supply a provider directory function today, or may supply the data, which would populate a provider directory. So try to get all those people to give us their best information about how to handle the challenge that we have as a workgroup.

Let me see if Micky has joined us yet. No? Okay. Let me press on to the second taskforce that we have launched on public health. And this is literally just yesterday this group has just begun to agree to do the work, so we really don't have any substance here yet. But Jim Buehler from CDC and Dave Ross have agreed to cochair this, which is extremely fortunate for us. And you see a number of other people who have agreed to be part of this taskforce.

Some of the issues, the problem that we're trying to solve, as it says on the next slide, is to enable providers to reach the stage one meaningful use criteria, as they pertain to population and public health categories in our matrix. We realize there's tremendous variation today in how public health departments are capable of supporting the goals of meaningful use with regard to the three things we've proposed in our work for meaningful use: immunization reporting, reportable conditions, and syndromic surveillance.

Our question is, what policy actions can be taken to facilitate public health agencies' abilities to meet the demand. In other words, there may not be a receptor site today to receive all the data we are asking meaningful users to supply to public health. So what is the infrastructure, and how integrated and accessible is that infrastructure to support the public health objectives that we have endorsed through the meaningful use program.

Here are the areas of initial conversation about where this taskforce may focus, and once they dig into this, of course, this may change significantly. First of all, as meaningful use with the three highlighted topics that are mentioned here, immunization registries, notifiable disease reporting, and syndromic surveillance. The second is standards to support the reporting across, as you see the list here on the right—CDC, NHIN, state systems, the public health information network—to harmonize the data submission requirements of all these entities in the public health space.

Secondly, again, as I mentioned, is the capacity to receive the data, particularly at a time when public health agencies are not flush by any means, and they're feeling great economic pressure. They don't necessarily have the resources to build the receptor sites that we are saying they need to have to receive the data we encourage them to have. How do we build uniformity in the data platforms? And how do we promote economies and interoperability across states and regions?

And then, lastly, leveraging the provider directory piece of this, public health systems also have their own provider directories. Can we harmonize these two elements of our charge, the provider directory piece with the public health piece in some more efficient manner? One other thing I'll just mention in the public health context, you probably all realize there is a tremendous layering of jurisdictions from local, county,

state, federal, public health agencies, and they all have their own infrastructure, funding, capacity, or lack of the same, and so it's not a simple matter to propagate a set of expectations or requirements around the public health information … can maybe amplify on that.

Our strategy on the public health taskforce is that our next meeting of this committee to be able to present to you some issues around public health capacity, at least kind of an environmental scan of what is the current state of capability in the public health community as a backgrounder to digging into how we can begin to have a set of key principles for public health reporting and information exchange with the public health sector. I think that is the review, and maybe here we'll just take some questions and discussion. I certainly welcome comments from other members here who are on either of those taskforces or the larger committee.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I already noticed, Judy, that our October 20th and November 19th agendas are really full so far. In the provider directory requirements slide, you had a number of functions, at least questions to answer. My question is, is the output of this group just become something, well, who adopts the output of this group, and who administered and who enforces it? And is it turned back to NHIN governance? Is it NHIN's governance role just to govern things that have already been set by various parties, or do they essentially have to adopt these things and sort of vet and endorse or incorporate them into what it means to participate in the NHIN?

David Lansky – Pacific Business Group on Health – President & CEO
I can give you two answers to that. One is, I don't know, and probably it begs the question of what the governance recommendations lead to in terms of implementation of a governance structure. I think what we see instead, to answering your question properly, is our realistic goal in the next few months is to articulate some high level principles that we think would be helpful to especially states implementing these structures so that they have something to work from that reflects some best thinking, best practice.

Secondly, to take something like what's on this slide and turn it into an outline of a topic, a discussion guide, if you'd like, or a topical guide. Here are the things you, a state coordinator or someone else in the provider directory business, need to address in order to stand up a viable provider directory. And then, thirdly, and this may be a few months down the road, begin to populate that outline with our own recommendations or best practices. But I think of this more as a guidance approach than a standard setting approach. However….

Paul Egerman – Software Entrepreneur
…an answer to that.

David Lansky – Pacific Business Group on Health – President & CEO
I will defer to my colleague.

Paul Egerman – Software Entrepreneur
The way I'd answer that question, Paul, is first of all, as David talks about this, it's important that we keep in mind one of the goals for the exchange workgroup is to sort of like be agnostic about which model is being implemented. So whatever gets implemented here has to work for these HIO organizations, but also has to work in directed exchange where there's no intermediary. The way I would hope that this group might be able to operate would be that it would establish like a set of concepts or priorities of what needs to be included in a provider directory, that the standards committee then would come up with a standards recommendation that fits that and that it would be eventually incorporated into certification criteria. If you go through all those steps, then the NHIN governance, whatever the governance group does should apply to it like any other standard would apply to it. But ultimately it becomes a standard for directory services, much as there are standards already that exist right now, say, for the Internet in terms

of DNS, in terms of how you do name identification on the Internet. So I think that's the way one could do that also.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Just to add, the state, the grants we've given to states for health information exchange basically require the state to put together a directory, so this is giving them technical assistance on how to do that and trying to assure that their directories are consistent across states. And whether that then becomes something we certify, given that certification right now applies to electronic records, not to the infrastructure that's maintained outside the record. I'm not sure, but this is one of many ways in which the Office of the National Coordinator is trying to support states and private entities in ways that we hope will lead to greater uniformity and reduced work for those state and private entities. Gayle?

Gayle Harrell – Florida – Former State Legislator
I would absolutely agree that this needs to be a major focus in how we go in HIE and the role of the states in every lever that the ONC has funding wise and whatever to assist them. Of course, as we all know, licensure in the real nitty-gritty of determining those things takes place at the state level. So whether you're an MD, a DO, or a lab or whatever, it's all licensed hospitals or licensed at the state level, so they need to be the ultimate arbiter down at the bottom level to certify these people.

The authentication process needs to be very much in place as well, so that we have that assurance that those are trusted entities, that we know who is who, and that when you access that person, you know it. And I think this is an absolutely critical element of what we're doing to assure safety and security, privacy and security in exchange. I think the levers are there. I hope the levers are there, and we, the Office of the National Coordinator needs to use those.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Richard?

Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP
Yes. Actually, I think that the question in health information exchange is what happens once the funding goes away and the business viability of the exchange. I would applaud the efforts to look at transactional type fee based things that could sustain these because we can all think of good reasons for the exchange to exist, and especially if it appears we're beginning to all say, if not directly, certainly indirectly that we're counting on the exchanges to play this directed exchange role for those who are not going to initiate it on their own unless there's a private effort that comes up. We did the state funding, as I understood it, to get feedback from the states, not only to build their directories, but to kind of give us ideas about how this might work in a state. I think all the help we can give to the business viability case for the exchanges and maybe define some of the roles that lead to that would be the primary focus of this group.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Just to add to that, the incentives for meaningful use and the disincentives associated with not being a meaningful user have the potential to create a business case if meaningful use also has robust exchange requirements. So potentially for big hospitals, there could be a lot of money on the table in the way of becoming a meaningful user, but then also avoiding the 2015 penalties. So to be a meaningful use and avoid penalties in 2016, 2017, 2018, you have to be moving information around. You're going to be looking for ways to do that, and it might be very much worth your while to support an infrastructure for exchange in your locality.

Once the burden of supporting that is spread among many entities that all need to participate in exchange, the burden on any one entity is pretty modest. So I know there's a lot of concern about this business case. I have a feeling—I can't prove it—that meaningful use will create the infrastructure. But once it's going there will be a reluctance to let it go away because all of a sudden doctors will find they can't share information in the way they used to, and they will be upset about that. And their state legislatures will hear about it, and the governors will hear about it, and there will have been an investment made that people will be reluctant to allow to decline and decay. I think that's the way we build, I guess, collective infrastructure in our society. That's a theory.

Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP
Just to follow up, David, just to follow up, we did see on the other side of it from the claims avenue going into insurance carriers that with that obvious incentive to submit claims electronically, the whole concept of a clearinghouse evolved as a business strategy that then grew on its own. All I'm saying is if a similar type seed were to be planted, and it can go along, that would go a long way toward helping with the combination of incentives there.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Art?

Art Davidson – Public Health Informatics at Denver Public Health – Director
Yes. I just wanted to clarify because I thought I heard something in David's comments earlier that sounded a little bit different than what Richard just described. The directed exchange would allow one provider to exchange with another, and Richard, in his statement said that that would be mediated through the HIO, HIE. Maybe I heard you say that that may not be necessarily a business model for the HIE, the directed part, and that the provisioning to the provider of the authentication service in saying who is in the directory, who has rights to do this, was the thing that you thought might be part of the business model. Did I get that right? Is the directed exchange mediated through an HIE, or is it just the fact that we have the address book that we're leaning on from the HIE to make the directed exchange?

David Lansky – Pacific Business Group on Health – President & CEO
I don't think there's a single answer to that question yet that I'm aware of. I've heard both scenarios …. I was speculating more that in terms of the business case issue that we just discussed, the directory itself is an asset. And, right now, there are many, many, many directories across the whole healthcare industry, each being maintained separately at great expense by different holders of that directory. So there may be an opportunity for an HIE to stand up an authoritative one, and reduce cost to other parties, which would then generate some of the sustainability David talked about, as opposed to a transaction based model for that cost savings. What that Micky?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, it is.

David Lansky – Pacific Business Group on Health – President & CEO
Great.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Good afternoon, everyone. Sorry for being late. I guess I would just amplify on David Lansky's response to say that I think that the answer to the question is yes. Meaning that I think that one of the things that we've found increasingly in the information exchange workgroup is that we have to remain humble to the wide variety of approaches that exist in the market today and that are going to exist in the future. And so I think you could see sort of the whole continuum of approaches where some are pure directed exchange, meaning that there is no intermediary involved in the transport, but would rely or benefit from access to a directory or directory service all the way to the other end where you could have a highly structured intermediary, health information organization that has a directory to serve not only the directed exchange that it may or may not host itself, but a variety of other functions that it hosts. And I think we'll see sort of everything in between those endpoints.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul, your tag was right there, and I didn't see it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I wonder if I could go expand on your comments as far as the Office of the National Coordinator by providing some guidance or best practice on these kinds of issues would catalyze and facilitate the work going on in the states. I think the next step though, it would be enabling if you continued on into either what Paul Egerman mentioned in terms of certification or NHIN governance actually oversees and

governs and enforces these because, like privacy, once you have a lowest common denominator, it makes it challenging to cross organization and state boundaries. In a sense, it's very enabling. I mean, it's very catalyzing and facilitating, but I think we'd almost all appreciate the next enabling step of making it uniform across states so that we can seamlessly cross boundaries.

We didn't have to do that before. All those things happened at a local organization. In a sense, what David Lansky said about all these silos, giving the silos the best practice and guidance can still have just more reinforced silos instead of the cross-channel communication. Is that a consideration, or is that possible for the next steps?

David Blumenthal – Department of HHS – National Coordinator for Health IT
This gets at authority and political will. The states have a lot of autonomy, and the federal government has not chosen in the past to preempt them on most issues, certainly on privacy. So whether we'd have the authority to enforce and, if so, how, the use of a particular type of directory, we can set standards for electronic health records. There is some question about whether we can set standards for other types of health information technology and what would constitute … but this is not health information technology, or maybe it is, but it's more a set of standards or ways of doing things.

There's some thought that we should be setting standards for the health information exchange and certifying health information exchanges. But a lot of this exchange work is not going to be done through health information exchanges, so I think it's a very interesting area with a lot of uncertainty about where we can go and what our authorities are. The advice of this committee would of course be of help if there were a consensus about what the approach should be and if that were informed by some understanding of the authorities available to the office.

Paul Egerman – Software Entrepreneur
Yes. I do think in sort of the model I described that the structure and the authority is there. That basically if you think about directed exchange, it's still communication from Provider A to Provider B. And so, to use ONC's certification authority to establish a nationwide standard about the directory structure, it's certainly very reasonable for directed exchange and for the HIOs who want to establish a business model. If their business model is a model that they're going to take care of somehow registering people and dealing with the various aspects of that directory, that's fine too. And there's actually a great analogy for that.

If you look at where the Internet works, there are these organizations called registrars. If you sign up for a URL, which I'm sure you've done several times, when you sign up for one of those things, you sign up with the registrar, but they insert you … into the various directories, and that's how they make their money. That's how they exist, and it works.

I do think there's a structure here where you could establish a national standard around this based on the idea that we're talking about directed exchange. I don't think that tramples on the state's autonomy at all. They don't have to offer that service if they don't want to, but it seems very logical that they would.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You may want to include in your recommendations to us that this directory for some … created through certification criteria or established, realized. Well, thank you, David, and thank you, Micky, for your thoughtful work on this. It is actually very important, as Gayle has said. I think the conversation has been illuminating as to ways in which we might actually move forward.

At this point, I think we'll move next to our last panel, our last presenter, and I want to welcome my colleague from the Department of Health and Human Services, Henry Claypool, who is the director of the Office on Disability, at the Department of Health and Human Services, a valued colleague. With him is David Baquis from the U.S. Access Board.

Henry Claypool – HHS – Director, Office on Disability

Thank you, David, and thank you for having us here today. In my role as the director of the Office on Disability, I oversee a number of tasks that are across the department and act on behalf of the secretary on particular disability related issues, and so Section 508 of the Rehabilitation Act is one that has come to my attention through the advocacy of agencies like the Access Board and others inside of the department. And so I'm here today again with David, who does represent an independent agency of the federal government called the Access Board that establishes standards that address barriers to people with disabilities that are in our society today. And we're here to urge you to adopt and promote accessibility standards around health IT that will really help people that are already working in the field continue to make the valuable contributions that they can and, when the system is more fully implemented, have something that doesn't require the industry and others to go back and make fixes to certain systems that because of the inaccessibility of certain features.

The best example that I know of is if you're familiar with Amazon and the Kindle that was recently released, it was reading books for folks, and it was a wonderful adaptation. And the problem was that there's a menu there, and it wasn't readable by assistive technology. So a blind person that uses a screen reader to see a screen can't access it. There was litigation, and eventually Amazon decided that they would go back and address this feature, and now I think they're all on the same page, and Amazon is moving forward. Of course, we're not at that stage in the game, and just wanting to raise this issue here before this policy committee today, and hopefully we can engage in some discussion of the issues. I know that David can enlighten you on what these standards are and how they really affect people. David?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Thank you, Henry. And thank you, everyone, for inviting us to speak to you today. This is actually the culmination of about four years of work to have this opportunity to present to you. My name again is David Baquis. I work for the U.S. Access Board, which is an independent federal agency, so we don't fall under a larger department. We're best known for having written the guidelines for the Americans With Disabilities Act, but we have authority under a number of other laws to write guidelines and standards for accessibility, and we also have specialization and technology, and that includes standards for health information technology. We also provide technical assistance and training on those standards, and we're governed by an official board of about 25 people, half of whom were appointed by the President of the U.S.

I thought it would be appropriate to start out with the concept of what accessibility is because this has been a source of confusion within the field of health. Sometimes people think if my patient has access to his or her health records, the records are therefore accessible because they can get to them. But when we say accessibility, we don't mean availability to the patient. We mean the removal of barriers, sometimes invisible barriers that you may not be aware of at first that actually makes it very difficult for them to use the technology. They may not be able to read it. They may not be able to use the buttons, things like that. This is actually routed in Civil Rights. It's part of the continuum of usability, the far end of the usability continuum, but the intention is to provide an assurance of nondiscrimination.

In answering the question, what is accessibility? One could say accessibility is conformance with Section 508 standards. These are accessibility standards that the Access Board wrote under authority of the Rehabilitation Act. About 25 years ago it was added, this section was added to the Rehabilitation Act. By law, this section applies only to federal departments and agencies, but the standards are out there, and people are using them, even outside the federal government. Other states have referenced them. Other countries are using them, and we recommend that these would also be folded into the HIT standards in the next iteration. They cover a wide range of technologies actually, so when we say HIT, we're thinking of Web, software, telephones, information kiosks, videos, computers, and a wide range of information technologies.

Who are we talking about? When we think of who benefits from accessibility, we don't just think of the patients, and we don't just think of improved health, but we also think of improved employment outcomes because we certainly want to be welcoming to clinicians with disabilities, if not at the outset of their career, maybe they develop a challenge later on their career. There are plenty of older people taking

care of older people, caregivers with disabilities, students. We've heard complaints from teachers have called us up and told us they're thinking of retiring early, but they don't know about some of the accommodations or accessibility available to them. And it's not just a blindness thing, which is the group perhaps most affected by inaccessibility of health records, but things like captioning can benefit people with hearing loss, and so when you meet these accessibility requirements, you just end up helping people with hearing, vision, speech, mobility, dexterity, and other disabilities.

This is the section of the slideshow that we severely cut. I've only got one slide giving you examples of barriers, but I could have included ten slides on this subject. But, sometimes to get to the health records, the first thing you have to go is get through a Web site portal, maybe register or sign in. That could be a problem right there. Our text equivalence provided for non-text elements, somebody who is blind using a screen reader that says the words out loud might just hear the word graphic when they encounter a photographic or illustration. But if there was an all tag or caption or some other kind of text equivalent, then they would know what that thing is that they can't see.

And how about tables? They might get stuck in a cell in the middle of a complex chart and not know what row or column they were in. But these are all solvable problems, and we've been solving them for the last ten years. This is nothing new. The Access Board issued the 508 standards in 2000 in the Clinton Administration.

One incentive for change you're already aware of, and that could be meaningful use if it gets folded into the next set of HIT standards. But there are other benefits. If an agency already has – when I say agency, I mean like an organization already has a policy of nondiscrimination, this is a way of proving it. I mentioned risk management. That means when you consider the cost of this, think not only of the possible added cost for accessibility, but also the money you save by not getting sued. And it's important to consider the fact that we're in a fishbowl of public policies right now.

If you're not already aware of it, I'd go to the Web site ada.gov, easy to remember. ADA for Americans with Disabilities Act, and take a look at the Department of Justice ANPRM, the Advanced Notice of Proposed Rule Making on Web sites. DoJ is considering regulating Web sites under Title II and Title III of the ADA, so providers such as hospitals and others may end up needing to make their Web site accessible, not just because of the positive incentive of meaningful use, but because they don't want to end up in litigation with DoJ civil rights attorneys.

This is the last slide with recommendations. The first is a values consideration, which is to elevate accessibility to the highest levels, so it's considered no less important than security and privacy. Then here's our primary recommendation, which is to fold accessibility into the health information technology standards, please. Actually, there's one bullet that's missing here, which is to recommend that NIST develop testing methods for conformance to accessibility standards, and then to fold accessibility into the certification process. And related to that would be, you'd need a process for qualifying the testers to be qualified to do accessibility testing, to fund research in accessibility, to develop a technical assistance and training …. If you require this, there's going to be hundreds and thousands of people out there with questions, and they can't all be calling the ONC office, so we really need to leverage the expertise and prepare the country for implementation.

To reduce burden, there's plenty of suggestions we have for doing this such as using offering tools that prompt you to create accessible content using evaluation tools that can help you flag errors if you want to check your Web sites. And there's plenty of information on this subject because the federal government has been implementing Section 508 for about a decade now. So does that leave plenty of time for questions? Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Questions? Yes, Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Thank you for the presentation. I have a question. Do you know if any current EMR or EHR vendor has complied with 508 recommendations?

Henry Claypool – HHS – Director, Office on Disability
Not to my knowledge. I haven't really done a survey of any systems that are out there in operation. David?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Only where the federal government would have required it for the federal government's purposes. Veterans Affairs may have some experience, for example.

David Blumenthal – Department of HHS – National Coordinator for Health IT
(Inaudible.)

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Yes, sir.

Henry Claypool – HHS – Director, Office on Disability
…all of our contracts got out for when we code our electronic health record are all 508 compliant. We would fully support that.

Paul Egerman – Software Entrepreneur
…both patients and also the employees working with the …?

Henry Claypool – HHS – Director, Office on Disability
For the providers right now.

Paul Egerman – Software Entrepreneur
Okay.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Lansky – Pacific Business Group on Health – President & CEO
One of our priority area … health disparities, and I can imagine, and one of the things we're trying to do is develop quality measures to assess whether we're making progress by introducing health IT in a way that reduces disparities. I can imagine there are populations of people who are most affected by some of the disabilities you all work on who are at risk for having poor access to health information and the associated services that depend on having access to better information.

Have you all thought about, or is there any recommendations or can we work with you to think about our quality measurement strategy, in other words, indicators that might tell us whether the deployment of health IT is helping to reduce the disparities in healthcare quality? I'm thinking off the top of my head about essentially from the patient experience point of view whether we are reaching with the tools we're all working on, are we reaching comparable numbers of people in the disability community, as we are in the rest of the community? Are there other methodologies like that that your programs work on that would help us?

Henry Claypool – HHS – Director, Office on Disability
Well, my office is a relatively modest resource. It certainly can connect with others that are very interested in engaging on the activities you've just identified. One specific example might be a population that's living with diabetes. As we know, it's relatively large. As vision goes, we've seen now the glucose monitors have large print, but as the vision fails further, we will have an auditory feature that's available. But we can imagine a number of scenarios where we'll have to be more sophisticated, and I think the type

of engagement that you suggest would really allow us to put the vision out in front of some of the issues that we'll run into, as we begin to address the health disparities that exist amongst people with disabilities.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
One of the slides I didn't show you was all the different conferences on this subject. And one of them was specific to measurement. And so maybe we can help you get access to the proceedings of that. HP2020 wants to fold this into an objective, Healthy People 2020, so people like Linda Harris at HHS, Margaret Campbell at the Department … helped organize this workshop because they can't have an objective that's not measurable a few times over a decade. And so they've asked that question, and we're going to continue to provide research recommendations on that. There's another workshop coming up in October.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Deven?

Deven McGraw – Center for Democracy & Technology – Director
Thank you all for your testimony. I've been working with some consumer groups out in California, and we developed a set of principles on health IT and accessibility was one of them. But I think, in our discussions, we conceptualized this more from a patient point of view, so patient access to personal technology tools like PHRs, patient's ability to interface their devices with electronic health records, and I don't know that we thought about it at all in the context of providers with disabilities who are really a primary, one of the primary, not the primary, but one of the primary audiences for us in terms of thinking of criteria for electronic health record systems, which are chiefly used not by patients, but by healthcare providers.

What do we know about the incidents of disability in that population that would help us sort of understand the scope of this a little bit, because we haven't done actually all that much on the patient facing tools. There are meaningful use criteria with respect to sharing data with patients, but not the extent to which the tools that patients themselves use, which are not part of the certification process presently. Sort of a different edge of this coin, which I don't think I thought of much until your testimony today.

Henry Claypool – HHS – Director, Office on Disability
Yes. I think it's crucial. I'm sure they're in the workforce right now, and they probably have answers to many of the questions that might be posed, and so they're a tremendous resource, I think, the sooner we identify them and tap into their expertise.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Send me an e-mail, and I'll link you up to a group that's specifically interested in disability issues in health education, and they might be able to provide some – you're right. The primary focus has been on patient access when it comes to accessibility, but we're just recognizing that, as a secondary benefit, there are the caregivers. I mean, a lot of people want to go in and find out how much of my healthcare spending dollars have I used up this year, or what are the latest prescriptions that I had filled at my pharmacy. It's not just the health physicians become more effective in making diagnoses.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
So you're clearly having an impact in what you're doing because this week I was on a pre-conference call with some folks from HRSA about a Webinar I was going to give, and the instructions I got were please don't do any graphics. And I said, why not? I was always taught when you do slides, the fewer words

and the more graphic displays the better. And they said, well, if they're too complex, we won't be able to meet the 508 standards. And embarrassingly, I said, what the hell are those. So I appreciate the fact that you're here and we're learning.

My question is, so what resources are there available to us who would want to make our Web sites or to make our patient portals and other things like that more accessible? Are there commercial companies out there that help people convert presentations, Web sites, and other things like that? Is this something that one can learn from a set of instructions? How do we learn to do this right?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
There are a tremendous amount of resources. There's section508.gov where there's free training courses. When you take them, by the way, you can print out a certificate. There's the Access Board's Web site with technical assistance materials. There are three people on staff at the Access Board full time who will provide free training to you in whatever vehicle works for you. It could be flying over in person, or it could be a Webinar or audio conference call, answering an e-mail. There's a whole network of for profit companies, accessibility consultants who would love to help you, and they could help you. They could help empower you so that your key techie staff can get trained and then be able to carry this forward internally, so you won't need to keep hiring somebody to help you. Does that help?

Neil Calman – Institute for Family Health – President & Cofounder
Tremendously.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
And I could provide you all these kinds of resources.

Neil Calman – Institute for Family Health – President & Cofounder
Thanks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
(Inaudible.)

M
Yes. Thank you. Again, I think, very timely and very, very helpful. Do you have any idea? I'm kind of looking at understanding the impact of other rulemakings on HIT. And it seems to me there's a certain amount of accessibility occurs through devices that can be provided. The other part of that then would be in the code, whether it's the Web site you write. Do you have any idea how the division of effort between those two components? And I'm just trying to look at how much change would one need to a Web site versus how much you could expect for a device to handle some of the interpretation.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
The standards make it very clear. First of all, when you provide accessibility, sometimes it's direct. So if you caption a video, I don't need any extra equipment. I can just see the captions right away. But in the case of people who are using assistive technologies such as video magnification software that makes it larger on screen or refreshable brail displays, you almost don't have to worry about the assistive technologies they're using, as long as you meet the standards. Once the text is exposed, then they can take care of it from their end as to how they want to utilize that. But you wouldn't have to provide speech output, for example. They would handle that on their end. It's a good question though.

Let's take e-learning courses. That's something else that might go up on a Web site. Some e-learning actually talks, but it doesn't have to. It could just be compatible with assistive technologies. So the simple answer is you have two choices. You can build in the accessibility, which is what you would need in an information kiosk. I can walk into a pharmacy, go to an information kiosk with health information. In that case, the solution has to be built into it. Nobody is bringing their assistive technology into the store. And that's a problem because they often use touch screen, which feels like a plate of glass. Some people who are blind don't know what the buttons are, and it probably doesn't have an audio jack for them to hear what it's saying.

M
Thank you.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
As I was listening to you all this morning, there are a few things that caught my mind. One is you were talking about governance for the NHIN, and you were talking about the importance of trust. In terms of trust by the disability community, part of how you get there is by providing accessibility. You talked about exchanges, and I have a copy of that proposed rule right with me now. We still have time to comment on that. And recommending that that office of HHS require the states receiving federal money to provide accessibility in exchanges might be yet another rule, as you talked about multiple rules at the same time. And my last thought was about enforcement. There might be enforcement through meaningful use, but there could also be enforcement through DoJ, as I was mentioning. So it's hard to keep accessibility out of the conversation. If I was on the policy committee, I'd be bringing it up all the time.

David Lansky – Pacific Business Group on Health – President & CEO
I have a question that follows up on what Neil mentioned in terms of graphics, for example. We actually had a hearing about the safety, as it relates to use of EHRs. And one of the issues is the ability to present a lot of information in an easily interpreted way. Clearly graphics is one of those powerful ways. Now that's both to the provider and to the patient. Neil's comment was to avoid graphs because it's hard to translate. You must have an answer for how do you deal with we're trying to enhance the value of information presented, yet be accessible, and how do you balance those?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Yes. Section 508 does not discourage graphics at all, as long as they can be made accessible. If we're talking about something with data points, like bar graphs, line graphs, that can all easily be made accessible, so that's not a problem. What's challenging is if you have a dynamic graph that shows the hurricane moving over the U.S., forest fires growing or something, but a static graph with mathematical data points is no problem at all.

Henry Claypool – HHS – Director, Office on Disability
What may have been the issue with the HRSA presentation is that there is no interface, so a blind person really can't see what's being presented to them, and someone would have to describe what is falling in a chart. And whether or not they had the ability to really run through each cell and describe what was populating it would be a challenge. However, with the technology, it can guide itself and find those locations and read from a particular cell. And we are facing tremendous challenges, and David is a good advocate. With our healthcare.gov Web site, we're loading, as you can imagine, rings of information from insurance companies, and many of these are presented to us in PDF format, and those really aren't able to be loaded onto our Web site. And for us to meet our 508 obligations, we're going to have to do some real work to figure out how to load this information onto our Web site in an appropriate fashion.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
You hit it. That was the main point. You just have to describe the graphics instead of saying, as you can see.

David Blumenthal – Department of HHS – National Coordinator for Health IT
It's an interesting question. You referenced the hurricane analogy or the weather map has analogies to medicine and especially imaging data, which is increasingly valuable and widely used and often has complex, three-dimensional colored and non-colored graphics. For example, measuring the dynamics of a beating heart, looking at flow across valves, those kinds of things. I'd be interested in how those kinds of images have been made accessible under the 508 standard. That may not be something you have at the tip of your tongue.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
That's one of the subjects that we're hoping you'll fund research on actually. But it's not all or nothing. I began to poke around, and I found one kind of image, and I forgot the exact name of it. It might have

been a retinox. It was something related to the eye and averaging software … to pinpoint the image, and the computer immediately turned the image into mathematical data. And so the minute you can use averaging software, there's the kind of algorithms that turn the visual image into data points, then it can be made accessible to somebody who blind. But most of the time that's not available.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So the 508 standards make allowance for things that have not yet been reduced to practice …?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Yes. Let me be responsive in that sense. We have something called exceptions. So there could be lack of commercial availability. It doesn't say it's not covered. It just says, at least for the federal government that it's okay to procure this item that's less than perfect because we looked around. We did our market research, and there was nothing else out there.

Henry Claypool – HHS – Director, Office on Disability
I believe, David, correct me if I'm wrong, there's a relatively high standard of what's called undo burden under the law if just making it accessible would be too costly. I don't think many folks have prevailed in pursuing that, but it is another exception.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
But that was a good question because we don't want 508 to be misunderstood, get a negative spin, and have that be the cause of not having interesting PowerPoint shows, not buying something you really need. We can still move forward and do business. We're just saying, in an ideal situation where we had two types of software the hospital could have bought, one was accessible and one wasn't, and they both met all of our other needs for security and privacy and everything else, why didn't we get the more accessible one?

Henry Claypool – HHS – Director, Office on Disability
We've crossed off the list.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So the next question I guess I would have is that for a non-disabled person, does the 508 process create any extra burden of work? Or is it something that's perfectly invisible to the non-disabled person, but can be activated for the disabled person?

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
You mean in terms of using it?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
I thought you meant in terms of like buying it and setting it up.

David Blumenthal – Department of HHS – National Coordinator for Health IT
No, I meant in terms of, you know, we are—one of the big issues that we face collectively in terms of federal policy is that there is a substantial burden imposed in many cases on providers who are target population for achieving the adoption of meaningful use of electronic health records, so we're acutely aware of what we're requiring of them. Now obviously it's not a burden on a disabled person to have accessibility that they didn't have otherwise. What I'm assuming is that the 508, meeting 508 requirements can be done such that if you're not disabled, there's no extra requirement on you, and if you are disabled, there's a route to accessibility.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
The simple answer is no. Once you've already developed an accessible environment, that shouldn't be causing some problems for people who don't have a disability. It's the other way around actually. When

you build a ramp into a building, then you've made it wheelchair accessible, and you've increased usability for the baby carriages, the shopping carts, the bicycles, the people with heart conditions, and so on. So this will, for the most part, accessibility improves usability for everybody else. If you have captioning, now I can see if. If English is my second language, and if I'm in a noisy environment, if I have a learning disability, and I need to read it and hear it at the same time, so I don't see this causing an annoyance to people without a disability. No.

Henry Claypool – HHS – Director, Office on Disability
In fact, I think, if we look into the field, we'd find some of the … around spreading 508 and its accessibility standards really come from the tech field, people that have grabbed onto this and really seeing how much of an impact they can have on people's lives and it's propagated out through, you can imagine the folks at Microsoft have really grabbed onto this, and they've now stimulated other activity in other areas. So we're hoping the same is true here.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Some people with handhelds have found that accessible Web sites actually load up faster in their devices than if it was more cluttered.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If there are no other questions, we're kind of at our time limit. We really appreciate you coming and sharing these insights with us. We put it on our agenda, and we will be back in touch, as we go forward with our second stage of meaningful use.

Henry Claypool – HHS – Director, Office on Disability
Thank you. We look forward to follow up with staff.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you.

David Baquis – U.S. Access Board – Accessibility Specialist in Technology
Thank you. We look forward to the collaboration.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think it's time for our public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes. We're ready for public comment. We do have a comment in the room. Mary, please identify your name and organization.

Mary McDonald – American Federation of Teachers – Director, Healthcare Div.
I would like to take a moment to explain to you the packets that were left at all your places. My name is Mary McDonald, and I'm the director of the healthcare division of the American Federation of Teachers. We represent 70,000 nurses and health professionals, and we're working also with SEIU and APSME, which represent hundreds of thousands of nurses and health professionals. I'm not sure the number.

We're very supportive of the work of this group, and we've very eager to work with you to insure the successful implementation of electronic health records. But on behalf of the nurses and professionals that we represent, I'd just like to convey some concerns. The purpose is really to ask your guidance in where the best venue would be to air these concerns and to determine whether it might be possible to do anything to address these concerns.

These concerns aren't new to you. I'm sure that you've heard them before. I had the opportunity to attend the care coordination hearing in July. And while a fair amount of time was spent on care coordination, I would say probably half the time was spent with panelists discussing their frustration at the design with the design of electronic health records and with the implementation process in the electronic health records. And for our nurses at least, concerns about the implementation, inadequate staffing

during the implementation and finding ways to insure that patients are kept safe during the implementation process.

In the packet, we provided to you the summary of a telephone poll of 600 nurses that was conducted in April by Peter Hart for our organization. But also more interestingly, I think there's a DVD in which we had some nurses who are at a large, northeast, New England hospital who sit around and talk about their go live and what it was like. And we edited the two-hour conversation down to ten minutes, and I think it's rather than having me try to, in a second-hand way, explain what it was like, I think it's of great value for you to listen to those nurses' voices and talk about what the process was really like. It's quite colorful, and they also have some excellent suggestions, I think, for ways in which the process could have been safer and easier.

We are aware that regulating the implementation of electronic health records is not within the scope of responsibility necessarily of this group. But as I said, we are looking for your ideas and your help in suggesting where this company could be had because I think the care coordination hearing shows that there are mounting frustration about finding a place at the national level that we can have this conversation among nurses, doctors, vendors, to determine what the barriers are to adoption of health information technology other than financial, what the barriers are. For example, our nurses will tell you that none of the physicians would take the training on how to learn the records before the go-live. And so the day of the go-live, the nurses had to not only – they had a full patient load with no extra staffing. They're learning a new system, and they're teaching the doctors the system at the same time. As a result, labs were delayed. Tests were delayed. Results were delayed. And as our nurses would say, patient care was not – luckily nothing terrible happened, but patient safety was not maintained at the level that we'd like to see it maintained at.

Again, our request of you, this is information I hope you will take the time to take a look at. And a request of you is where, at the federal level, might we be having this conversation to determine if there is anything, that what tools we might have available. Perhaps it's best practices. Perhaps there are other tools that would come out of such a conversation, but where could we have this conversation? We'd look forward to working with you to determine that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thanks.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have one comment on the phone. Would you please identify yourself?

Tom Leary – HIMSS – Senior Director Federal Affairs
Hello. This is Tom Leary with HIMSS. I wanted to thank Dr. Blumenthal and the committee for the excellent conversation today, particularly the accessibility activity. As my friend … Cohen from the Department of Defense has been saying for years, there's an opportunity for consumers, providers, administrative staff, etc. to have more access to health IT and, therefore, job creation, and just job improvement is out there. I applaud the conversation and look forward to the opportunity to engage with the group in the future.

The other item that I'd like to highlight is that early in the conversation today, you talked about meaningful use readiness, and as many of you know, we've had the electronic medical record adoption model for the last several years. With respect to that, it's a consensus survey of the hospitals and what they've purchased. Where we see the, with respect to purchasing or meaningful user, HIMSS has started asking questions that are more pertinent to the meaningful use of the products, not just yes I have it in my facility. And we look forward to reporting to the committee and to the department and just the public, as we hit more robust information on that end in the coming months and in the new year. That's my comment. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. Leary. And we have one final commenter on the phone. Could you please identify yourself?

Robin Raiford – Allscripts
This is Robin Raiford from Allscripts. Just a comment about the general talk today about consumers if the time is now to maybe reach out a bit to consumers to start, as Deven had said, working with consumer groups in California and that. I just had a thought about the PHIP survey that's done by the census bureau where they go out and ask questions about if you're in certain programs, if there couldn't be a few questions added to the PHIP survey so that they're asking about does your doctor have an electronic healthcare record.

Do you want to use an electronic healthcare record? Because as we go on this journey for stage two and stage three, ultimately to have quality and the results that we want, it's got to take cooperation besides obviously the trust of the consumer, but the participation of the consumer to take accountability for their care, for their chronic diseases, and just a thought that that might be a way to initially start it.

Then based on what the first commenter said as well, if there could be some way to have champions for the cause of people who have had successful go live to share that and have a venue to share that to basically not be drowned out by the people who are struggling, but hear the success stories of people who have done it. And as of the comments were made that it's not impossible, but it's hard work, and when you get there, it's a great result.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Robin. That's the end of the comment period. Turn it back to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you all again. We'll see you on October 20th when we have a very full schedule. Safe travels, everyone.

Public Comment Received During the Meeting

1. What is the likelihood of the HIE communication to go down? Technology is awesome, but at times access or communication to technology is hindered.

2. Regarding HIE sustainability; it is true providers will want to continue sharing data. Also important to address the risk factor "if HIE" using defined technology that we are establishing 'stops'! How will data management being addressed 'if' nationally and statewide discontinuance of HIE is probable?

3. Mara Robertson: regarding governance enforcement; would the HIPAA penalties play a role in this?